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AN APPRAISAL OF HUMAN EXPERIMENTATION IN INTERNATIONAL LAW AND PRACTICE: THE NEED FOR INTERNATIONAL REGULATION OF HUMAN EXPERIMENTATION

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I. INTRODUCTION

Human experimentation can be broadly defined as anything done to an individual to learn how it will affect him.¹ Its main objective is the acquisition of new scientific knowledge rather than therapy. If an experiment is ultimately beneficial to others or even to the subject himself, this does not mean that therapy served an important purpose.² There are three distinguishable types of cases involving the treatment of human subjects. The first is traditional treatment which uses normal and approved methods and techniques for therapeutic purposes. The second is research treatment, which means that a sick person is treated with new methods and techniques primarily for therapeutic purposes. This is sometimes called therapeutic experimentation. The third is re-

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¹ Bowker, *Experimentation on Humans and Gifts of Tissue: Articles 20-23 of the Civil Code*, 19 MCGILL L.J. 161, 164 (1973).

² *Id.*

search which consists of treating individuals with new procedures and drugs for purely scientific purposes. This may be labelled "research experimentation."³

If medical progress were to depend solely upon the scientific by-product of experimentation conducted incidental to therapy, medical science and human health care might, figuratively, still be in the dark ages. Throughout medical history, research experimentation has played a central role in the development of knowledge which is beneficial to human health. The influence of human experimentation permeates not only medicine and the other biological sciences but also behavioral, sociological, political, economic, and military endeavors. Because human experimentation deals with effects upon large numbers of people, experimenters possess the potential to enhance or diminish the welfare of mankind.⁴ Since this potential may result in willful, reckless or inadvertent acts harmful to human beings, human experimentation is also a proper concern for the international criminologist. Moreover, because of the focus upon individual conduct rather than state action, experimentation creates relatively neutral political concerns so that sovereign nations can meet without fear of retaliation or loss of power and reasonably expect to reach agreement on regulatory schemes. The prospects for success are important in our time, when international policy-makers find themselves with inadequate measures to implement and enforce international laws.⁵ Since mutual agreement among sovereign nations is necessary to secure enforcement, the potential for international cooperation in human experimentation must be fully explored. In this manner adequate measures can be developed to protect human subjects from abuse.

II. HISTORICAL SURVEY OF HUMAN EXPERIMENTATION

The history of human experimentation dates to some of the oldest writings on earth. The effects of inoculation were studied by the Chinese of the Sung Dynasty in 590 B.C. and were recorded in a Sanskrit text, studied in India in the second and third centuries A.D.⁶ The prac-

³ Giesen, *Civil Liability of Physicians for New Methods of Treatment and Experimentation*, 25 INT'L & COMP. L. Q. 180, 188 (1976).

⁴ See generally L. CLENDENING, SOURCE BOOK OF MEDICAL HISTORY (1960); F. GARRISON, AN INTRODUCTION TO THE HISTORY OF MEDICINE (1913).

⁵ See Mueller & Besharov, *The Existence of International Criminal Law and Its Evolution to the Point of Its Enforcement Crisis*, in 1 A TREATISE ON INTERNATIONAL CRIMINAL LAW 1 (M. C. Bassiouni & V. Nanda, ed. 1973) [hereinafter referred to as INTERNATIONAL CRIMINAL LAW]. There is increasing recognition of the need to expand and strengthen the international regulation of human experimentation by means of a convention in the form of existing human rights conventions. See Schwarzenberg, *Pour un Code International de Deontologie Medicale*, Le Monde, June 14, 1979, at 8, col. 4. See notes 327-29 & accompanying text *infra*.

⁶ Bollet, *Smallpox: The Biography of a Disease—I*, RESIDENT AND STAFF PHYSICIAN, Aug. 1978, at 47, 48.

tice in ancient Persia was for the king to consign condemned criminals to scientific experimentation. The Ptolemies permitted this practice in Egypt, and it existed in Renaissance Pisa.⁷ When Hippocrates asserted that epilepsy is not an act of divine intervention but an ordinary disease, he set the stage for the study of neurology and mental disease.⁸ Galen stressed experimentation in conjunction with observation, formalizing medical experimentation in Western society about 1800 years ago.⁹ Harvey's dominance in the seventeenth century supplanted the earlier dominance of Galen. In particular, Harvey carried out controlled experiments on animals and man in order to demonstrate that blood circulates through the heart and lungs.¹⁰

The number and diversity of experiments on human subjects has accelerated since the mid-eighteenth century. Some of the more noteworthy examples are: Lind's highly controlled study in 1757 demonstrating that citrus fruits cure scurvy; Jenner's publication in 1798 of experimental results showing the value of vaccination against smallpox; Davy's beautifully planned studies in 1799, giving rise to modern anesthesia, which was followed, after much controversy, by Morton's first public demonstration of anesthesia in 1846;¹¹ Pasteur's discovery that inoculation with attenuated rabies virus induced immunity to bites from rabid animals;¹² and Korotkoff's studies in 1905 which measured arterial blood pressure.¹³ The zeal to acquire new knowledge often prompted the experimenter to use himself as subject, sometimes with severe results. For example, in 1767 John Hunter inoculated himself with the pus of gonorrhea to prove that the disease is transmissible. He succeeded but also contracted syphilis from the inoculation. Walter Reed subjected himself to the effects of yellow fever virus in order to discover the manner in which it spreads to cause epidemics.¹⁴ Self-experimentation provides an important model for human experimentation: the researcher harmed only himself; he did so voluntarily, and with full knowledge and consent. Further, he did it with highly altruistic motivation.

Human experimentation has achieved many spectacular successes,

⁷ H. BEECHER, *RESEARCH AND THE INDIVIDUAL: HUMAN STUDIES* 5 (1970).

⁸ *Id.*

⁹ *Id.* at 5-6.

¹⁰ *Id.* at 6.

¹¹ *Id.* at 6-8.

¹² L. CLENDENING, *supra* note 4, at 378.

¹³ Segall, *How Korotkoff, the Surgeon, Discovered the Auscultatory Method of Measuring Arterial Pressure*, 83 *ANNALS INTERNAL MED.* 561 (1975).

¹⁴ H. BEECHER, *supra* note 7, at 8-9.

such as the control of polio¹⁵ and the reported worldwide eradication of smallpox.¹⁶ It has, on occasion, been an incentive to subjects to attain important benefits and avoid death or severe harm but not without great risk. For example, in 1722 inmates in Newgate Prison volunteered to be inoculated for smallpox as an alternative to hanging. All survived and were released. However, experiments also have resulted in severe and sometimes permanent harm or death to subjects. In 1898 Freund nearly killed his subject while experimenting with X-rays to remove hair on moles. In 1857 carbon tetrachloride was used as a human anesthetic even though a few animal studies would have shown it to be unsuitable. In 1905 Fletcher used the inmates of an insane asylum to study beriberi. Some forty-three patients contracted the disease, and eighteen died. The study is considered important and is often cited, but no one has commented at length on the ethical problems created. In 1902 a series of experiments were performed on a dozen civil service employees in order to determine the effects of food preservatives, but there was no evidence of concern for the subjects' welfare.¹⁷ From 1932 to 1972 the infamous "Tuskegee experiment" took place using black males to determine the natural course of syphilis even though treatment had existed for decades.¹⁸ Certainly the most demonic but among the most worthless studies of all were those conducted by Nazi physicians on Jewish civilians, prisoners of war and others interred in concentration camps.¹⁹

Unfortunately, abuses did not end with World War II. In *Hyman v. Jewish Chronic Disease Hospital*, the court denied a petition by the director of a hospital membership corporation to inspect the medical charts of twenty-two cancer patients who had been injected with live cancer cells to determine if their bodies' responses to such cells was the same as for healthy patients. Petitioner argued that the patients were either incompetent or not adequately informed to give consent. Significantly, the court noted that written informed consent would be required for similar experiments in the future.²⁰ There also are the studies by Milgram (1963, 1964, 1974) which were intended to determine whether subjects would continue to inflict pain upon their "victims" (who were

¹⁵ See C. FRIED, *MEDICAL EXPERIMENTATION: PERSONAL INTEGRITY AND SOCIAL POLICY* 147-48 (1974).

¹⁶ Bollett, *supra* note 6, at 47; Henderson, *Smallpox—Epitaph for a Killer?*, 154 NAT'L GEOGRAPHIC 796 (1978).

¹⁷ H. BEECHER, *supra* note 7, at 6-11.

¹⁸ Ingelfinger, *The Unethical in Medical Ethics*, 83 ANNALS INTERNAL MED. 264, 265 (1975); HARRISON'S PRINCIPLES OF INTERNAL MEDICINE 718, 723 (Isselbacher, et al. eds. 9th ed. 1980).

¹⁹ See notes 218-25 & accompanying text *infra*.

²⁰ 21 App. Div. 2d 495, 251 N.Y.S.2d 818 (1964). See notes 285-86 & accompanying text *infra*.

actually confederates in the experiment) when ordered to do so by experimenters despite the "victims" protestations. The study concluded that the great majority of subjects did as ordered; apparently, however, many were upset because of their conduct during the experiment, and the ethics of that type of study were subsequently called into question.²¹ While human experimentation has advanced man's knowledge and improved his life, it has failed to keep pace in the development of the safeguards needed to protect human subjects.²²

This is not to say that concern for the welfare of subjects is without historical and ethical precedent, for just as the origins of human experimentation have ancient roots, so, too, do the antecedents of society's burgeoning awareness that experimentation on man creates ethical problems. For example, Celsus, practicing in Alexandria in the third century B.C., spoke out against the dissection of living men.²³ The oath attributed to Hippocrates in the fifth century B.C. has been viewed as giving advice on experimental diagnosis and therapy. Other documents such as Percival's code of 1803, Beaumont's code of 1833, and Claude Bernard's personal code of 1856 express concern about the ethical issues of human experimentation.²⁴ Moreover, a number of traditions view the medical practitioner's role as a moral enterprise. For example, the inscription on the Asklepion of the Acropolis exhorts physicians to treat all men as brothers. The Hindu oath instructs physicians to assist all people as if they are relatives. The Chinese code of Sun Ssumiao (7th century A.D.) affirms that all people are to be treated equally. And the prayer of Maimonides ends with a request that God support the physician in his task for the benefit of mankind.²⁵ The credo basic to these ethical statements is *primum non nocere*: "Above all do no harm." A poignant analogy is that the physician does not stand in relation to his patient as a carpenter stands before a block of wood. An ethical duty arises between the physician and the patient whereby the former is not morally free to exercise his skills in any manner he desires; rather he is bound by the origin, nature and purpose of his enterprise to use them primarily for the patient's benefit.²⁶

²¹ See, e.g., Dickens, *Information for Consent in Human Experimentation*, 24 U. TORONTO L.J. 381, 398-99 (1974); S. MILGRAM, OBEDIENCE TO AUTHORITY (1974); see generally Daube, *Legal Problems in Medical Advance*, 6 ISRAEL L. REV. 1 (1971); Rosenthal, *On the Social Psychology of Psychological Research*, 51 AM. SCIENTIST 268 (1963); Seeman, *Deception in Psychological Research*, 24 AM. PSYCHOLOGIST 1025 (1969).

²² See Beecher, *Ethics and Clinical Research*, 274 NEW ENGLAND J. MED. 1354 (1966).

²³ H. BEECHER, *supra* note 7, at 10.

²⁴ *Id.* at 12.

²⁵ See Curran, *The Proper and Improper Concerns of Medical Law and Ethics*, 295 NEW ENGLAND J. MED. 1057 (1976); Jonsen, *Do No Harm*, 88 ANNALS INTERNAL MED. 827 (1978).

²⁶ Jonsen, *supra* note 25, at 828.

Governments have also entered the arena of human experimentation by recognizing its great social and economic implications and devoting huge tax revenues to its development.²⁷ Politicians and heads of state have utilized and exploited the popular appeal and potential for population control in human experimentation,²⁸ and military strategists have sought to use experimentation to achieve victory.²⁹ Not surprisingly, the role of governments in this field of science causes serious concerns. The works of novelists express the fear of widespread government control of people's minds and behavior through experiments intended to perfect psychosurgical techniques, psychological conditioning and psychotropic drugs.³⁰ Some commentators have argued that these fictional accounts may one day exist in reality as a potential result of experimentation recently conducted in psychosurgery.³¹ Others have objected to governmental approval of the coercive use of prisoners, orphans, and the insane.³² Physicians have reportedly performed experiments on behalf of their governments in order to scientifically study the effects of torture.³³ Unchecked government sanctioning of human ex-

²⁷ See Confrey, *PHS Grant-Supported Research with Human Subjects*, 83 PUB. HEALTH REP. 127, 130 (1968). The United Nations has expressed concern that governments should use science and technology for the benefit of mankind. See Declaration on the Use of Scientific and Technological Progress in the Interests of Peace and for the Benefit of Mankind, G. A. Res. 3384 (XXX), 10 November 1975.

²⁸ See notes 215-25 & accompanying text *infra*.

²⁹ E. RUSSELL, *THE SCOURGE OF THE SWASTIKA* 214 (1954).

³⁰ See, e.g., A. BURGESS, *A CLOCKWORK ORANGE* (1962); M. CRICHTON, *THE TERMINAL MAN* (1972); A. HUXLEY, *BRAVE NEW WORLD* (1932); G. ORWELL, 1984 (1949); E. ZAMIA-TIN, *WE* (1924).

³¹ See Mearns, *Law and Physical Control of the Mind: Experimentation in Psychosurgery*, 25 CASE W. RES. L. REV. 565 (1975). The author argues that by allowing uncontrolled psychosurgical research, our deep reverence for the self and respect for the individual is being relinquished to the psychosurgeon to remake or remold. *Id.* at 593. See, e.g., Peters & Lee, *Psychosurgery: A Case for Regulation*, 1978 DET. C. L. REV. 383, 386-87, who argue that experimental psychosurgery should only be performed where there is known therapeutic benefit to the patient and where the degree of risk is determined in light of the seriousness of the condition to which the therapeutic purpose is addressed. See also Kaimowitz v. Dept. of Mental Health, 1 MENTAL DISABILITY L. REP. 147, 42 U.S.L.W. 2064 (Mich. Cir. Ct. 1973), which involved a psychosurgery research project of uncertain benefit on a subject in compulsory confinement. The surgery was prohibited despite approval by two committees and informed consent procedure. Cf. Nat'l Comm. for the Protection of Human Subjects of Biomedical and Behavioral Research, HEW, *Use of Psychosurgery in Practice and Research: Report and Recommendations*, 42 Fed. Reg. 26,318 (1977). This report implicitly recognized that the efficacy of psychosurgery has not been sufficiently proven so as to be characterized as accepted treatment. *Id.* at 26,329. This same conclusion was stated explicitly in *Kaimowitz*. See Note, *Return to the Cuckoo's Nest: An Examination of the National Commission Report on Psychosurgery*, 6 HOFSTRA L. REV. 941, 954 (1978).

³² See Daube, *supra* note 21, at 8. See also Yeo, *Psychiatry, the Law and Dissent in the Soviet Union*, 14 REV. INT'L COMM. JUR. 34 (1975); Young-Anawaty, *International Human Rights Norms and Soviet Abuse of Psychiatry*, 10 CASE W. RES. J. INT'L L. 785 (1978).

³³ Sagan & Jonsen, *Medical Ethics and Torture*, 294 NEW ENGLAND J. MED. 1427 (1976). The authors refer to a report in the Manchester Guardian of May 3, 1974, in which photos

perimentation can result in little or no consideration for the well-being of the subject. The final stage in the corruption of human experimentation was the deliberate Nazi crimes against humanity, performed in the name of scientific advancement, as disclosed at the Nuremberg trials.³⁴

III. EVOLUTION OF LEGAL CONTROL OF HUMAN EXPERIMENTATION

Human experimentation becomes most critical in the field of medicine, where the relationship between the experimenter and his subject is on a direct individual basis and the experiment may jeopardize the subject's health or life. Medical experimentation is therefore of vital interest to law and society.³⁵ Moreover, the traditional doctor-patient relationship³⁶ has been affected by the pressures of experimentation so

appeared of prisoners in Portugal taken during interrogation. These prisoners were made available to prison doctors who wanted to study the effects of torture. Medical experimentation can cross the line into torture when no useful scientific purpose is served and the subject is transformed into a suffering victim. *But see* Gellhorn, *Violations of Human Rights: Torture and the Medical Profession*, 299 NEW ENGLAND J. MED. 358 (1978) (discussing international medical seminar for purpose of preparing casebook on effects of torture for use when legal redress is possible). *See generally* Bassiouni, *An Appraisal of Torture in International Law and Practice: The Need for an International Convention for the Prevention and Suppression of Torture*, 48 REVUE INT'L DE DROIT PÉNAL 17 (1977) [hereinafter referred to as *The Prevention and Suppression of Torture*].

³⁴ *See* 1-2 TRIALS OF WAR CRIMINALS BEFORE NUREMBERG MILITARY TRIBUNALS UNDER CONTROL COUNCIL LAW NO. 10, THE MEDICAL CASE (1974). *See also* Weinschenk, *Nazis Before German Courts*, 10 INT'L LAW. 515 (1976). The author states that no instance has been conclusively established in which any German was punished for refusing to participate in atrocities and that members of Nazi terror organs knew that they were engaged in criminal enterprises, dictated by the fanatical aims of the Nazis. *Id.* at 526-27. The evidence thus indicates that investigators participated in these crimes and so are not blameless. However, if left to their own devices, they would not have permitted some of these atrocities to occur. One of the most important justifications for international criminology is its role in the development of methods for encouraging and reinforcing individuals who resolve voluntarily to comply with basic humanitarian principles. The Nuremberg tribunal and the war crimes trials at Tokyo made a beginning by recognizing the principle of individual responsibility for the commission of crimes against humanity. *See* Ryu & Silving, *International Criminal Law—A Search for Meaning*, in INTERNATIONAL CRIMINAL LAW, *supra* note 5, at 26-29 and the actions of the League of Nations through its *Draft Statute for an International Court* [1954] U.N.Y.B. 430.

³⁵ Much creative thinking toward understanding the problems involved with human experimentation has occurred in the field of medicine. The medical profession has, of course, established a long history of genuine concern for the welfare and rights of patients. *See* notes 23-26 & accompanying text *supra*. It still enjoys a modicum of confidence and trust from society. *See generally* H. BEECHER, *supra* note 7, at 165-213; Levine, *Boundaries Between Research Involving Human Subjects and Accepted and Routine Professional Practices*, in SYMPOSIUM ON HUMAN EXPERIMENTATION 3 (R. Bogomolny ed. 1976) [hereinafter cited as HUMAN EXPERIMENTATION].

³⁶ In its original form, the doctor-patient relationship was one of mutual confidence and trust, aimed at the care and treatment of the sick. This was the therapeutic relationship. It dominates the attitudes and activities of the majority of physicians in practice today. Their contribution to new medical knowledge is limited, but they nevertheless contribute by using their training and powers of observation to aid in the accumulation of clinical data. *See* Page,

that now the physician is also an investigator, and the patient is also a subject.³⁷ The traditional physician regarded his patient primarily as a subject for treatment rather than for experimentation. Thus, efforts were directed at responding to the patient's therapeutic needs.³⁸ Nevertheless medical knowledge advanced, often through surprising clinical discoveries, followed by crude laboratory and animal studies and finally through the therapeutic use of experimental findings, usually upon desperately ill patients.³⁹

In the twentieth century the physician-therapist has been "cross-bred" with the ever-emerging scientific investigator whose attitudes and loyalties are conditioned more by the laboratory than by his patients and whose preoccupation is, therefore, with designing and conducting effective experiments to solve problems not readily unravelled by simple and unsystematic clinical observations. As the investigator discovered numerous therapeutic measures, he became indispensable to medical research. Thus, a "hybrid" has developed, the physician-investigator. His perspective is determined by the twin priorities of care for the sick and the desire for continued medical progress through scientific inquiry. Those priorities may conflict and create ethical problems when scientific inquiry can only be made (usually in final stages of a study) on human beings.⁴⁰ Additionally the advent of statistical methodology at the turn of the twentieth century with its sample size requirements leads to an increase in the number of subjects needed for a valid and publishable experiment. Furthermore, the manageability of information afforded by computer technology encouraged the gathering of ever larger amounts of data through experimentation. Thus, the potential data base of human subjects has continued to expand.

On the whole, the new physician-investigator continues to develop and refine medical knowledge without sacrificing the welfare of the patient. Academic societies were founded to establish rules of basic conduct and to facilitate the free exchange of information.⁴¹ A kind of

Comments on the Pharmacologic Woof, Warp, and Web, 278 NEW ENGLAND J. MED. 364 (1967). Cf. Rhoads, *Medical Ethics and Morals in a New Age*, 205 J.A.M.A. 517 (1968); Silvermen, *Informed Consent*, 38 PEDIATRICS 373 (1966).

³⁷ The physicians who conducted the early experiments that opened the era of scientific investigation had tools significantly different from those in use today. See notes 6-17 & accompanying text *supra*.

³⁸ See generally I. LADIMER & R. NEUMAN, *CLINICAL INVESTIGATION IN MEDICINE: LEGAL, ETHICAL AND MORAL ASPECTS* (1963); *EXPERIMENTATION WITH HUMAN SUBJECTS* (P. Freund ed. 1970).

³⁹ See H. BEECHER, *supra* note 7, at 5-14.

⁴⁰ See generally C. FRIED, *supra* note 15, at 5; Lasagna, *A Researcher's Perspective*, in *HUMAN EXPERIMENTATION*, *supra* note 35, at 21.

⁴¹ See, e.g., Dyck, *Kennedy Medical Ethics Program at Harvard*, 295 NEW ENGLAND J. MED. 1132 (1976).

“common law” governing most physician-investigators developed through administration of the Hippocratic Oath.⁴² Thus, primary emphasis continued to be placed upon the control of illness and the maintenance of a therapeutic rather than an investigative relationship. If, however, the emphasis in medical science shifts from therapy to investigation, the momentum for scientific discovery may thereby undermine the traditional morality of the doctor-patient relationship to the extent that the patient’s personal rights and welfare will be violated.⁴³

The doctor-patient relationship should be distinguished from medical experimentation in its purest form. In the latter the controlled clinical experiment does not purport to benefit the subject; instead the subject helps the medical scientist. Although the medical experiment is part of the quest for the knowledge necessary to alleviate human suffering, the medical scientist creates a dangerous illusion by believing that by virtue of this principle he can carry out experiments without the consent of the subjects. Medical treatment and controlled medical experimentation are closely related but distinctly different activities. Both have an equal claim to social approval, but they should be regarded differently by the law because they differ in character.⁴⁴ The medical scientist may try to justify non-consensual experimentation on the grounds that any given patient is the beneficiary of countless prior experiments on others, and, therefore, submission to experimentation is part of the “price” he pays for these benefits, thereby benefiting future persons. Although, as a theory, this helps to explain the attitudes of some doctors toward patient-subjects, the difficulty of quantitatively and qualitatively measuring the extent of the benefits derived from pre-

⁴² One version of this Oath formulated by the World Medical Association in Geneva in 1948 reads as follows:

Now being admitted to the profession of medicine I solemnly pledge to consecrate my life to the service of humanity. I will give respect and gratitude to my deserving teacher. I will practice medicine with conscience and dignity. The health and life of my patient shall be my first consideration. I will maintain the honor and the noble traditions of the medical profession. My colleagues will be as my brothers. I will not permit considerations of race, or religion, nationality, party politics or social standing to intervene between my duty and my patient. I will maintain the utmost respect for human life from the time of its conception. Even under threat I will not use my knowledge contrary to the laws of humanity. These promises I make freely and upon my honor.

By this Oath the physician promises to protect the patient’s privacy, preserve his dignity and practice medicine ethically and morally. These elements are incorporated into codes of ethics of professional societies throughout the world. L. CLENDENING, *supra* note 4, at 14.

⁴³ See H. BEECHER, *supra* note 7 (listing some twenty-two published clinical studies in which, usually by accident but sometimes by intent, violations of subjects’ rights occurred). See also Hyman v. Jewish Chronic Disease Hospital, 21 App. Div. 2d 495, 251 N.Y.S.2d 818 (1964); Wasmuth, *Physician’s Liability When Using New or Experimental Drugs*, 31 CLEV. CLIN. Q. 61 (1964).

⁴⁴ Larsen, *Legal Aspects of Medical Experimentation*, 20 SCANDINAVIAN STUD. IN L. 163, 169 (1976).

vious experimentation is so great that the theory is dangerously close to a rationalization.

State involvement in human experimentation has also influenced the evolution of controls. Because the state has assumed an increasingly active role in the discovery of medical knowledge through various agencies and as a result of funding various projects,⁴⁵ its policies concerning citizens as subjects of experimentation is critical. If the individual is perceived as a government chattel instead of the beneficiary of government action, then individual rights could be sacrificed whenever the State's "possessory interests" in its citizens are combined with a purely scientific-investigative attitude on the part of researchers. These conditions coalesced in Nazi Germany leading to crimes by physicians which came to international attention at Nuremberg.⁴⁶

The Nuremberg medical prosecutions⁴⁷ offer the scientific and legal communities important lessons regarding the dangers to individual safety inherent in human experimentation and the controls needed to maintain a balance between advances in medical knowledge and the need to protect individuals. Besides the principle of individual responsibility and the showing of moral delinquency which emerged from the war crimes proceedings, the trials highlighted the basic notion that humans could be used as experimental subjects for purely scientific investigations without regard to therapeutic advantage. This concept was instilled in the Nazi physicians who received their training at European universities and who came from every stratum of the German medical profession.⁴⁸ From the start, the Nazi experiments were in violation of existing German law and the code of ethics of the German medical community,⁴⁹ but by degrees, the Nazi philosophy eroded the resistance of the German medical profession until German law was ignored without legal effect or social opprobrium.⁵⁰ What began, perhaps, as well-inten-

⁴⁵ See Fredrickson, *Biomedical Research in the 1980's*, 304 NEW ENGLAND J. MED. 509 (1981).

⁴⁶ A. MITSCHERLICH & F. MIELKE, DOCTORS OF INFAMY: THE STORY OF THE NAZI MEDICAL CRIMES xi-xii (1949); Enloe, *The German Medical War Crimes—Their Nature and Significance*, 30 RHODE ISLAND MED. J. 801 (1947); Ivy, *Nazi War Crimes of a Medical Nature*, 139 J.A.M.A. 131 (1949); Ivy, *The History and Ethics of the Use of Human Subjects in Medical Experiments*, 108 SCIENCE 1 (1948); Mellanby, *Nazi Experiments on Human Beings in Concentration Camps in Nazi Germany*, 1 BRIT. MED. J. 148 (1947); Mulford, *Human Experimentation*, 20 STAN. L. REV. 99 (1967).

⁴⁷ See J. APPLEMAN, MILITARY TRIBUNALS AND INTERNATIONAL CRIMES 142-43 (1954). See also W. SHIRER, THE RISE AND FALL OF THE THIRD REICH 979-91 (1960).

⁴⁸ The excuse given by the experimenters in the latter case for not first testing their experiments on animals first was that animals were either too expensive or not conveniently available. Katz, *The Education of the Physician-Investigator*, in EXPERIMENTATION WITH HUMAN SUBJECTS, *supra* note 38, at 297.

⁴⁹ Weinschenk, *supra* note 34, at 518-19.

⁵⁰ Ivy, *Nazi War Crimes of a Medical Nature*, *supra* note 46, at 131. Another factor which has

tioned scientific inquiry became distorted beyond all reasonable ethical limits. Even though the defendant physicians at Nuremberg argued that their studies led to useful information, this argument was rejected, both on its own terms and in light of the harm done to the subjects.⁵¹

The Nuremberg medical trials also suggest that the magnitude of the crimes committed would have been impossible without the involvement of the State. Scientists were, in part, persuaded to engage in experiments because of the knowledge that the subjects available to them were actually prisoners already scheduled for disposal by the State.⁵² This practice hideously dramatizes the notion that the state is free to treat its nationals in the manner it chooses because it perceives itself as the source of all rights, and therefore as beyond the reach of law, rather than regarding rights as inalienable, that is, not subject to arbitrary cancellation by the State.⁵³ The Nazi barbarism is a stark illustration of the common-sense notion that as state oppression grows, individual rights decline.

Even in more benign systems, there is the potential danger to personal welfare resulting from society's need for pure scientific investigation and its acceptance of the philosophy of justifiable personal sacrifice for the public good.⁵⁴ The combination of such conditions not only

been attributed to the moral destruction of the German medical profession under Hitler is the notion that "the welfare of the armed forces was the supreme good and anything that helped the armed forces was the supreme good and anything that helped the armed forces was right." *Id.* at 144. See also Enloe, *supra* note 46, at 804.

⁵¹ Ivy, *Nazi War Crimes of a Medical Nature*, *supra* note 46, at 132.

⁵² 3 RECORD, THE TRIAL OF GERMAN MAJOR WAR CRIMINALS 160-61 (1946).

⁵³ The atrocities reported at Nuremberg were only a few of many examples in political history of misappropriation of individual rights for public expediency. One of the earliest such events recorded concerns the sacrifice of youths to provide blood for Pope Innocent VIII, in a futile attempt to restore the aging pontiff to vigorous youth. Beecher, *Scarce Resources and Medical Advancement*, in EXPERIMENTATION WITH HUMAN SUBJECTS, *supra* note 38, at 88. Another example was provided by Queen Caroline of England, who, before allowing her own children to be inoculated with cow pox, had the vaccine tested on prisoners and children of the poor. Beecher, *Experimentation in Man*, 169 J.A.M.A. 461, 469 (1959). The Nazi brutality presented, ironically in Germany, a contradiction of Germany's greatest philosopher, Immanuel Kant, whose central theory of ethics held that people should never be treated as means but only as ends. I. KANT, FOUNDATIONS OF THE METAPHYSICS OF MORALS 47 (L. Beck trans. 1959).

⁵⁴ See EXPERIMENTATION WITH HUMAN SUBJECTS, *supra* note 38, at xviii. Even under more benevolent forms of government, the rights of the individual may be subordinated to the public health, safety or welfare. See generally Macklin & Sherwin, *Experimenting on Human Subjects: Philosophical Perspectives*, 25 CASE W. RES. L. REV. 434 (1975). The most common expression of this concept is the right of nations to conscript male citizens for the armed forces in time of armed conflict. There are also more subtle ways in which the State exacts personal sacrifice for the public good, without allowing freedom of choice, as for example, the right of the State to confiscate personal property through eminent domain, taxation and compulsory inoculation before entry into school or before travel abroad. See also Dickens, *supra* note 21, at 408, who suggests that in time of national emergency, individuals may be asked to participate

poses the dangers of using the ends to justify the means but could also result in the failure by states or scientists to establish effective laws for the proper conduct of scientific investigation.⁵⁵

A major issue at Nuremberg was defining the criteria for ethical human experimentation. Consequently, the Articles of the Nuremberg Tribunal developed as the first formal attempt to create a legal framework governing human experimentation. These Articles provide:

1. The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.
The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs, or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.
2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.
3. The experiment should be so designed and based on results of animal experimentation and a knowledge of the natural history of the disease or other problems under study that the anticipated results will justify the performance of the experiment.
4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
5. No experiment should be conducted where there is an *a priori* reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.
6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.
7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability or death.
8. The experiment should be conducted only by scientifically qualified

in experiments without their consent in order to develop new drugs or forms of treatment as matters of vital national or international urgency.

⁵⁵ H. BEECHER, *supra* note 7, at 192-200.

persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.

9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.
10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill, and careful judgment required of him, that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.⁵⁶

The concepts of Nuremberg were reevaluated at the meeting of the World Medical Association in Helsinki, in June of 1964, and were incorporated into the Code of Ethics on Human Experimentation of the World Medical Association.⁵⁷ Helsinki was the second formal attempt to place human experimentation within a legal framework.⁵⁸ Those meeting at Helsinki emphasized that the Declaration of Geneva by the World Medical Association,⁵⁹ include the words: "The health of my patient will be my first consideration," and be binding upon the physician. They also pointed out that the International Code of Medical Ethics⁶⁰ declares that "any act or advice which could weaken physical or mental resistance of a human being may be used only in his interest." Based upon those underlying concepts the final Code embodied the following basic principles:

1. Clinical research must conform to the moral and scientific principles that justify medical research and should be based on laboratory and animal experiments or other scientifically established facts.
2. Clinical research should be conducted only by scientifically qualified persons and under the supervision of a qualified medical man.
3. Clinical research cannot legitimately be carried out unless the importance of the objective is in proportion to the inherent risk to the subject.
4. Every clinical research project should be preceded by careful assess-

⁵⁶ See J. APPLEMAN, *supra* note 47, at 147-48; Beeson, Bondy, Donnelly, & Smith, *Panel Discussion: Moral Issues in Clinical Research*, 36 YALE J. BIOLOGY & MED. 455-56 (1964).

⁵⁷ Anonymous, *World Medical Association, Human Experimentation: Code of Ethics of the World Medical Association*, 2 BRIT. MED. J. 177 (1964); Declaration of Helsinki, adopted first by the World Medical Association in 1964, *Declaration of Helsinki: Recommendations Guiding Doctors in Clinical Research*, 197 J.A.M.A. 32 (1966).

⁵⁸ Bryant, *the Burgeoning Law of Medical Experimentation Involving Human Subjects*, 8 JOHN MARSHALL J. PRAC. & PROC. 19, 20 (1974).

⁵⁹ Anonymous, *The Declaration of Geneva, 1948: A 1971 Reappraisal*, 2 MED. J. AUSTR. 735 (1971).

⁶⁰ Adopted by the Third General Assembly of the World Medical Association at London, October, 1949.

ment of inherent risks in comparison to foreseeable benefits to the subject or to others.

5. Special caution should be exercised by the doctor in performing clinical research in which the personality of the subject is liable to be altered by drugs or experimental procedure.⁶¹

The World Medical Association also defined, for the first time, a fundamental distinction between clinical research, which is essentially therapeutic, and "pure" clinical research, which is primarily for the purpose of acquiring scientific information with little anticipated therapeutic value to the subject.⁶² Different guidelines were formulated for each situation:

A. *Clinical Research Combined with Professional Care*

1. In the treatment of the sick person the doctor must be free to use a new therapeutic measure if in his judgment it offers hope of saving life, re-establishing health or alleviating suffering. If at all possible, consistent with patient psychology, the doctor should obtain the patient's freely-given consent after the patient has been given a full explanation. In case of legal incapacity, consent should also be procured from the legal guardian; in case of physical incapacity, the permission of the legal guardian replaces that of the patient.
2. The doctor can combine clinical research with professional care, the objective being the acquisition of new medical knowledge, only to the extent that clinical research is justified by its therapeutic value for the patient.

B. *Nontherapeutic Clinical Research*

1. In the purely scientific application of clinical research carried out on a human being, it is the duty of the investigator to remain the protector of the life, health, and privacy of that person on whom clinical research is being carried out.
2. The nature, the purpose, and the risk of clinical research must be explained to the subject by the investigator.
- 3a. Clinical research on a human being cannot be undertaken without his free consent, after he has been fully informed; if he is legally incompetent, the consent of the legal guardian should be procured.
- 3b. The subject of clinical research should be in such a mental, physical, and legal state as to be able to exercise fully his power of choice.
- 3c. Consent should as a rule be obtained in writing. However, the responsibility for clinical research always remains with the research workers; it never falls on the subject, even after the consent is obtained.
- 4a. The investigator must respect the right of each individual to safeguard his personal integrity and privacy, especially if the subject is in a dependent relationship to the investigator.

⁶¹ See note 56 *supra*.

⁶² See H. BEECHER, *supra* note 7, at 279.

- 4b. At any time during the course of clinical research, the subject or his guardian should be free to withdraw permission for research to be continued. The investigator or the investigation team should discontinue the research if in his or their judgment it may, if continued, be harmful to the individual.⁶³

Clearly, the scientists who met at Helsinki could not condemn all human experimentation. They recognized that medical science had advanced beyond the point where simple observation and accumulation of random clinical data could satisfy the requirements for effective inquiry into the causes and treatment of human disease. It was also apparent that the Helsinki Code would serve only as a broad guideline, against which the investigator must compare his conduct in relation to the subject-patient.⁶⁴

The Code of Ethics on Human Experimentation of the World Medical Association has been adopted by the American Medical Association and, in modified but similar forms, by most professional medical organizations throughout the world.⁶⁵

IV. ISSUES OF PROTECTION UNRESOLVED BY EXISTING CODES

The Nuremberg Code has been criticized as imposing a rigid set of legalistic demands. It is argued that the Code, in an attempt to provide for all contingencies, unduly restricts the investigator by requiring him to anticipate and provide for every situation and by demanding the impossible in some instances.⁶⁶ The Helsinki Code, on the other hand, is said to provide only broad concepts that fail to effectively protect humanitarian interests because it is inapplicable in many circumstances.⁶⁷ Moreover, terms used in both codes lack specificity and are therefore susceptible to definition and interpretation by the investigator according to his own experiences. The fluid concepts of these codes also fail to answer several questions concerning the protection of human subjects.

A. CONSENT

The adequacy of the subject's consent required by these codes is uncertain. Article One of the Nuremberg Code provides that consent be "voluntary," without coercion and "informed." But those criteria are objectionable because the subject's truly informed consent cannot be obtained since the results of experiments are not known beforehand.⁶⁸ Un-

⁶³ See note 56 *supra*.

⁶⁴ See H. BEECHER, *supra* note 7, at 278-79.

⁶⁵ Shaffer, *Medical Ethics*, 1 EDITORIAL RESEARCH REP. 461, 470 (1972).

⁶⁶ H. BEECHER, *supra* note 7, at 279.

⁶⁷ Hill, *Medical Ethics and Controlled Trials*, 1 BRIT. MED. J. 1043 (1963).

⁶⁸ H. BEECHER, *supra* note 7, at 278-79; cf. Hill, *supra* note 68, who argues that there are

like informed consent in the medical malpractice setting,⁶⁹ there is no norm for the conduct of a "pure" scientific experiment. The investigator is in no position to "inform" his subject of potential complications due to the limited knowledge available regarding an experimental drug or therapeutic technique.⁷⁰ Nevertheless, with the "pure" scientific investigation, consent which does not meet the criteria of "informed" should not relieve the investigator of liability.⁷¹

A related question is the ability of the intended experimental subject to "consent" to invasion of his person or to procedures the results of which are uncertain, of dubious benefit or clearly harmful. For example, no individual may consent to "euthanasia murder."⁷² Consent to abortion was also once prohibited in the United States,⁷³ but now it may not be lawfully performed as an elective procedure after viability in the absence of therapeutic indications, which has been defined by the United States Supreme Court as the time at which the attending physi-

experimental situations involving human subjects, as for example, in industrial psychology experiments, in which the subject's informed consent is undesirable and should not be sought. For a discussion of the problems of consent and compulsory confinement of mental patients in Britain, see Gostin, *The Merger of Incompetency and Certification: The Illustration of Unauthorized Medical Contact in the Psychiatric Context*, 2 INT'L J.L. & PSYCHIATRY 127 (1979). See generally Harding & Curran, *Mental Health Legislation and Its Relationship to Program Development: An International Review*, 16 HARV. J. LEGIS. 19 (1979). For the problems of consent to sterilization see Comment, *Sterilization Abuse: A Proposed Regulatory Scheme*, 28 DEPAUL L. REV. 731 (1979).

⁶⁹ Informed consent as it exists in medical malpractice should not be confused with the consent sought of a normal individual subjected to a "pure" scientific experiment. In the context of malpractice, the physician is required to follow a known pattern of therapy on a sick individual. Liability is imposed and remedies set for failure to conform to a pre-arranged routine that is known and predictable. Treatment is explained to the patient before it is administered, and the patient accepts it knowing the anticipated results as well as the possible complications. W. PROSSER, LAW OF TORTS 103-04 (4th ed. 1971).

⁷⁰ The remedy of insurance schemes is intended to provide compensation when injury results from inadequacy of informed consent. Adams & Shea-Stonum, *Toward a Theory of Control of Medical Experimentation with Human Subjects: The Role of Compensation*, 25 CASE W. RES. L. REV. 604 (1975); Silverstein, *Compensating Those Injured through Experimentation*, 48 CONN. B.J. 398 (1974); Simonis, *On Behalf of Victims of Pseudo-Medical Experiments: Red Cross Action*, extract from the INT'L REV. RED CROSS, Geneva (January, 1973); Spiro, *Constraint and Consent*, 293 NEW ENGLAND J. MED. 1134 (1975). See also Friedman, *Health Hazards Associated with Recombinant DNA Technology: Should Congress Impose Liability Without Fault?*, 51 S. CAL. L. REV. 1355, 1374 (1978).

⁷¹ See Dickens, *supra* note 21, at 393; Dickens, *Contractual Aspects of Human Medical Experimentation*, 25 U. TORONTO L.J. 406, 424 (1975). See also Vaccarino, *Consent, Informed Consent and the Consent Form*, 298 NEW ENGLAND J. MED. 455 (1978). But see Shrank, *Determinism and the Law of Consent—A Reformulation of Individual Accountability for Choices Made Without "Free Will"*, 12 SUFFOLK L. REV. 796, 821 (1978) (arguing that consent is only a relatively important factor).

⁷² See generally Kutner, *Euthanasia: Due Process for Death with Dignity; The Living Will*, 54 IND. L.J. 201 (1979).

⁷³ See generally M. BASSIOUNI, SUBSTANTIVE CRIMINAL LAW 236-39 (1978); G. FLETCHER, RETHINKING CRIMINAL LAW 373-79 (1978); W. LAFAVE & A. SCOTT, HANDBOOK ON CRIMINAL LAW 530-32 (1972).

cian judges that there is a reasonable probability of the fetus's ability to survive outside the womb, with or without artificial support.⁷⁴

B. VOLUNTEERS

The legality of using involuntary subjects in experiments has often been challenged. The subjects who are usually coerced into participating are (1) imprisoned convicts, (2) inmates of mental hospitals or domiciliary institutions, (3) patients in "free" or "clinic" hospitals, often affiliated with medical, educational, or research facilities, (4) indigent patients, (5) service men, and (6) children, including the mentally handicapped and (7) fetuses. Subjects in all but the last category may be coerced, often by subtle means, because of their vulnerable station in life.⁷⁵ In some instances—for example, with children or mental patients—the subject may lack the ability to fully understand an explanation of the proposed experiment.⁷⁶ The potential for abuse is further complicated by the low public interest in such individuals. The coerced subject, therefore, often reacts to subtle pressures by complying, rather than by making an intelligent and informed decision. Likewise, prisoners may become "volunteers" because of their inability to resist material inducements. This is also a means by which experimenters from a prosperous industrialized country can obtain subjects in a developing country. By contrast, medical institutions, which are charged with responsibility for teaching competent clinical medicine and exist primarily for therapy of sick patients, perform their research within the therapeutic doctor-patient relationship, which thereby minimizes the danger of infringing upon the patient's rights. Such protection remains even if all therapy is broadly regarded as quasi-experimental. However, subjects outside of medical institutions are not always ensured of similar protection.⁷⁷ Thus, greater focus on protection of subjects in the context

⁷⁴ *Colautti v. Franklin*, 439 U.S. 379 (1979). For a summary of the changes in the law of abortion since *Roe v. Wade*, 410 U.S. 113 (1973) and *Doe v. Bolton*, 410 U.S. 179 (1973), see Comment, *Viability and Fetal Life in State Criminal Abortion Laws*, 72 J. CRIM. L. & C. 324 (1981). For a discussion of the failure of the law to tell the physician how to balance the woman's interests in a safe and legal abortion against the state's interest in protecting fetal life and the consequent criminal or tort liability that may be imposed, see Note, *Criminal Liability of Physicians: An Encroachment on the Abortion Right*, 18 AM. CRIM. L. REV. 591 (1981).

⁷⁵ See generally U.S. NAT'L COMM'N FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, HEW, RESEARCH INVOLVING CHILDREN 21-26 (1977); H. BEECHER, *supra* note 7, at 52-78; C. FRIED, *supra* note 15, at 61-63; Curran, *Research on Children*, 299 NEW ENGLAND J. MED. 1001 (1978); Daube, *supra* note 21, at 10; Martin, *Ethical Standards for Fetal Experimentation*, 43 FORDHAM L. REV. 547 (1975).

⁷⁶ Daube, *supra* note 21, at 10.

⁷⁷ See Curran & Beecher, *Experimentation in Children: A Reexamination of Legal Ethical Principles*, 210 J.A.M.A. 77 (1969); Hodges & Bean, *The Use of Prisoners for Medical Research*, 202 J.A.M.A. 177 (1967); Martin, Arnold, Zimmerman & Richart, *Human Subjects in Clinical Research—A Report of Three Studies*, 279 NEW ENGLAND J. MED. 1426 (1968); McDonald, *Why*

of detention, custody or control is needed since freedom of choice is unlikely in such environments.

C. CONVENIENCE OF EXPERIMENTAL SUBJECTS

Three classes of experimental subjects may be especially vulnerable to experimentation conducted without regard for their rights. These classes include aborted fetuses, "fabricated" individuals created *in vitro*, and terminal patients. The rights of aborted fetuses and terminal patients may be disregarded because life expectancy is certain rather than indefinite. The effect of the experimental act on the survival of the subject is thereby disregarded, since the propriety of the act is said to depend upon whether the decision to abort or to regard a patient as terminal is irrevocable. Such individuals thus become experimental subjects mainly because of convenience and not necessarily because the experiment is meritorious.⁷⁸ Even with scientifically sound experiments involving abortions, investigators have reasoned that the parents' decision to abort degrades the fetus into nothing more than a piece of tissue. So long as it appears that the experiment will benefit "society" or other fetuses and that the aborted fetus alone will be harmed and not survive, it is said to follow that such research should be approved. But if the experiment may increase the chances for survival of the aborted fetus, already determined to be unwanted by its parents, such research, it is argued, should be condemned. This line of reasoning reverses the canons of medical ethics, which require that experimental procedures produce therapeutic benefit to the subject.⁷⁹

Fabricated individuals are those who are conceived and maintained

Prisoners Volunteer to be Experimental Subjects, 202 J.A.M.A. 511 (1967); Schreiner, *Liability in Use of Investigational Drugs*, 185 J.A.M.A. 259 (1963). See generally U.S. NAT'L COMM'N FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, HEW RESEARCH INVOLVING PRISONERS: APPENDIX TO REPORT AND RECOMMENDATIONS (1976) (Dep't of H.E.W. Pub. No. (05) 76-132).

⁷⁸ See Appel, *Ethical and Legal Questions Posed by Recent Advances in Medicine*, 205 J.A.M.A. 513 (1968); Brown, *Ground Rules for Physicians Who Evaluate Drugs*, 203 J.A.M.A. 137 (1968); Freund, *Ethical Problems in Human Experimentation*, 273 NEW ENGLAND J. MED. 687 (1965); Friend, *Clinical Evaluation of Drugs*, 187 J.A.M.A. 348 (1964); Martin, *supra* note 75, at 568-69. The notion of "implied consent" persist in every milieu involving humans as experimental subjects and must be dealt with whenever "pure" scientific inquiry without immediate benefit to the subject is contemplated. See H. BEECHER, *supra* note 7, at 25-26.

⁷⁹ P. RAMSEY, *THE ETHICS OF FETAL RESEARCH* 37-40 (1975). Any fetus whose mother intends to carry it until birth is not included here because its life expectancy is not definite. See also Curran, *Experimentation Becomes a Crime: Fetal Research in Massachusetts*, 292 NEW ENGLAND J. MED. 300 (1975). Condemned prisoners could also be regarded as "terminal" and in need of the same protection as aborted fetuses and dying patients. See Daube, *supra* note 21, at 8.

for a limited time *in vitro*. Society may tend to regard such subjects⁸⁰ as not fully entitled to the protections accorded to persons conceived in the ordinary way. Cynical and opportunistic attitudes may ultimately develop as a result of decreased legal protection provided to aborted fetuses, terminal patients and fabricated individuals, which may ultimately weaken society's sense of lawfulness and respect for the sanctity of life.⁸¹ An individual should not become less human, that is, his physical integrity and right to be free from exploitation should not be less valued in an experimental setting, when the time of death is known or the manner of conception is artificial.

D. ADEQUACY AND EFFICIENCY OF EXPERIMENTAL DESIGN

Whether an experiment is designed adequately and efficiently to answer the questions it raises is frequently overlooked as a possible source of violation of the subject's rights. The investigator must be obliged to show that the risks his subjects undergo are justified by the usefulness of the anticipated data, the so-called "risk/benefit ratio." Relevant experiments must be well-designed in order to obtain information efficiently, with risks to subjects minimized. Finally, if the experiment poses real dangers to human subjects, the investigator should be required to demonstrate to an appropriate administrative or judicial body that the information is not obtainable in any other feasible manner. That is, he must show that the purpose of his experiment is to acquire knowledge about a certain class of individuals - for example, fetuses or mental incompetents - and not that this class is simply convenient. Although some leeway is essential for the investigator, experiments potentially dangerous to subjects should be conducted only after thorough pre-clinical evaluation.⁸²

E. REPEATED EVALUATION OF ONGOING HUMAN EXPERIMENTS

The original purpose of an experiment may become altered or the subjects's rights may be suppressed or overlooked under pressure of the changing requirements of an ongoing research project. Once the investigation is underway, the need to direct it with regard to its purposes and the subject's rights weigh heavily upon the investigator. The personal

⁸⁰ The Supreme Court holds that someone is not a "person" until birth. *Roe v. Wade*, 410 U.S. 113 (1973).

⁸¹ Tuchler, *Man-Made Man and the Law*, 22 ST. LOUIS U.L.J. 310, 325 (1978). See also Dinstein, *Science, Technology and Human Rights*, 5 DALHOUSIE L.J. 155, 161-62 (1979); Reich, *'Test-Tube' Babies*, 27 NEW PHYSICIAN 39 (1978). One commentator cites an ethically objectionable Finnish study in which nonviable fetuses were decapitated to study the effects of certain chemicals. Brock, *Fetal Research: What Price Progress?* 1979 DET. C. L. REV. 403, 406.

⁸² Curran & Beecher, *supra* note 77, at 78.

integrity necessary for the investigator to comprehend the moral and ethical dimensions of the experiment as it progresses is greatly influenced by his education and philosophical perspective. Significant assurance of protection of the subject's rights during the course of an experiment must be given by the investigator himself because substantive and procedural guidelines cannot encompass every contingency.⁸³ However, national and local review committees must also be charged with evaluation of ongoing research. If it is reasonably certain that the original purpose has been altered or that the subject's rights may be violated and the investigator has not been apprised of these problems or has not taken adequate steps to alleviate them, then the review committee must step in to protect the subjects.⁸⁴

F. STATE INVOLVEMENT

The state is inevitably called upon to balance the public good against individual rights. This problem is critical in human experimentation, especially with respect to matters affecting entire communities—for example, control of communicable diseases, preschool inoculations, preventive health care and birth control. The power of the state ensures compliance with public health regulations. It also gives rise to moral and ethical questions concerning government agencies and administrators, whose actions may be aimed at protecting the public good but also might introduce risk to the individual.⁸⁵ Therefore, moral and ethical considerations necessary for proper human experimentation cannot be the entire responsibility of the principal investigator, but must be shared by the state administrative structure under which he functions.

G. CHEMICAL AND PHARMACEUTICAL EXPERIMENTATION OR A TRANSNATIONAL BASIS

The potential of harm to human subjects exists in the context of experimentation with chemical and pharmaceutical products by companies from developed countries performed on nationals of third world countries. The testing of such substances may produce side effects and result in great harm. Companies, by supplying monetary compensation beforehand to all volunteers, could be released from responsibility for harmful effects. Monetary inducement makes individuals in developing nations especially vulnerable. Even intelligent and fully informed con-

⁸³ Wakerlin & Sembower, *Legal Aspects of Medical Research*, 141 J.A.M.A. 429 (1949); Wolfensberger, *Ethical Issues in Research with Human Subjects*, 155 SCIENCE 47 (1967).

⁸⁴ Confrey, *supra* note 27; Shannon, *The Advancement of Medical Research: A Twenty-Year View of the Role of the National Institutes of Health*, 42 J. MED. EDUC. 97 (1967).

⁸⁵ *See* Cowan, *Human Experimentation: The Review Process in Practice*, 25 CASE W. RES. L. REV. 533, 552 (1975).

sent is easier to obtain, despite the high degree of risk involved. An implicit element of duress exists because economic inducements are difficult to refuse. As a result, subjects may not be adequately protected because most developing countries lack the control mechanisms which are found in industrialized countries. Although this problem has not been explicitly addressed at the international level, some precedent for regulation exists by analogy to other situations.⁸⁶ One effective solution is to apply the regulatory standards of the country involved which provides the most protection to the subjects and is most likely to be the developed country.⁸⁷ These standards, along with those of the medical profession, should provide greater control of the chemical and pharmaceutical industry.

V. CODIFICATION OF HUMAN EXPERIMENTATION IN THE UNITED STATES

Since 1960 the United States has seriously attempted to establish statutory criteria for human experimentation⁸⁸ and has actively partici-

⁸⁶ One basic doctrine of international law is that a state may not use its territory in any manner which is harmful to the territory of another state. This principle was applied in *United States v. Canada (Trail Smelter Case)*, 9 ANN. DIG. 315, 35 AM. J. INT'L L. 684 (1941). There, the United States government made certain representations on behalf of the State of Washington. Citizens of Washington alleged that noxious fumes emitted from a smelter located in Trail, British Columbia, were causing considerable damage to property and livestock. Canada was eventually held responsible for most of the damage. The *Trail Smelter* case implies that citizens of one nation may not engage in any activity which is likely to cause harm to the citizens or territory of another nation. This principle was at issue in *Great Britain v. Albania (Corfu Channel Case)*, [1949] I.C.J. 4. There persons of allegedly unknown origin placed mines in the waters of an international strait that lay within the territorial waters of Albania. One British destroyer was sunk and others damaged in attempting to cross these waters. The Court held Albania responsible for the consequences of activities of persons within its territory and ordered Albania to pay reparations. The principle which emerges from the *Corfu Channel* case is one which approaches absolute responsibility. This principle is also advanced in the Convention on International Liability for Damage Caused by Space Objects, G.A. Res. 2777, 26 U.N. GAOR, Supp. (No. 29) 25, U.N. Doc. A/8429 (1971). Article II provides for "absolute liability" to pay compensation by the launching state for damages caused by its space object. These three examples indicate that one nation would be responsible for damages to the people or territory of another nation. Likewise, a drug company from a developed country may be held liable for damages caused to experimental subjects in a Third World country. This is one means of monitoring the activities of drug companies abroad. For a detailed discussion of this problem, see Zilinskas, *Recombinant DNA Research and the International System*, 51 S. CAL. L. REV. 1483, 1490-91 (1978). Developing countries are also intent upon bringing the benefits of science and technology, including financial gain, to their peoples and accordingly may refuse to let human rights considerations impede progress. Dinstein, *supra* note 81, at 163.

⁸⁷ See U.S. Foreign Corrupt Practices Act of 1977, 15 U.S.C. §§ 78a note, 78m, 78dd-1, 78dd-2, 78ff, which provides that the standards of the country of origin apply to corporations or their subsidiaries or affiliates or if they are controlled in fact through management or ownership, *i.e.*, of more than 25 percent of the outstanding shares of stock.

⁸⁸ Curran, *Governmental Regulation of the Use of Human Subjects in Medical Research: The Ap-*

pated, with some regrettable exceptions,⁸⁹ with other nations in attacking medical and health problems of international scope. These international attempts at medical cooperation furnish a useful starting point for establishing an international code for regulation of human experimentation. An international code is a logical progression from the strong influence of the Nuremberg and Helsinki Codes and from the broad doctrinal foundation already laid for cooperation among sovereign nations in this largely unexplored area of international law.⁹⁰ A survey of the legislation reveals that lawmakers have perceived the need to regulate human experimentation and have responded with a variety of schemes.⁹¹

A. AMERICAN CASE LAW ON HUMAN EXPERIMENTATION

Prior to 1960 there was little common law in the field of human experimentation. There were no recorded attempts to regulate research organizations or investigators except on a voluntary basis, and there was

proach of Two Federal Agencies, in EXPERIMENTATION WITH HUMAN SUBJECTS, *supra* note 38, at 402, 409-49.

⁸⁹ The credibility of such United States participation has recently been called into question by the Nestles infant formula incident where the United States was the only United Nations member not voting against the distribution of a milk product linked to an increased incidence of infant death and malnutrition in developing countries. See TIME, June 1, 1981, at 26. See also *The Infant Formula Controversy: An International Health Policy Paradigm*, 95 ANNALS INTERNAL MED. 383 (1981) (criticizing negative U.S. vote on World Health Organization's "International Code of Marketing of Breastmilk Substitutes" and urging increased participation by health care professionals in international health problems).

⁹⁰ This doctrinal foundation is still unorganized and scattered throughout several disciplines. However, development of international regulatory schemes has been found to progress according to a discernable pattern. In the first phase, scholars postulate certain philosophies in their writings. Second, these writings become the premises of more specific theoretical writings. These in turn give impetus to certain international undertakings. Then the formulation of specific normative prescriptions follows. Finally, sanctioning devices are shaped. Bassiouni, *An Appraisal of the Growth and Developing Trends of International Criminal Law*, 46 REVUE INT'L DE DROIT PÉNAL 405, 409 (1974). As this study seeks to demonstrate, the field of human experimentation has ripened to the point at which international controls are feasible.

⁹¹ For an analysis of the constitutional standards which statutes governing scientific research must meet in the United States, see Robertson, *The Scientist's Right to Research: A Constitutional Analysis*, 51 S. CAL. L. REV. 1203 (1978). The author argues that the pursuit of scientific research is protected by the fourteenth amendment as a fundamental personal liberty, by the right to freedom of association, and primarily by the first amendment by fulfilling the individual's interest in personal expression and society's interest in the receiving of information necessary for social and political decision-making. *Id.* at 1209-15. Direct prohibition of certain kinds of research by the State is permissible if the means used by researchers to acquire scientific knowledge intrude on interests with which the state has legitimate concern. *Id.* at 1253. Thus, first amendment protection for scientific research is aimed at safeguarding the scientist's private research goals and methods from direct State interference. If the State restricts research out of fear of the knowledge that may be produced, it must meet the strict standards of prior restraint and incitement which with respect to protected speech are based on content. *Id.* at 1278. For a discussion of constitutional issues in the context of medical treatment, see Peters & Lee, *supra* note 31, at 388-405; Note, *supra* note 31, at 964-69.

no litigation for malpractice or criminal actions against research organizations or personnel. Generally, however, the legal climate was hostile toward research, which was regarded as deviating from accepted methods. The doctor "experimented" at his peril.⁹² When litigation finally came, the courts viewed experimentation by the clinician responsible for the competent cure of the patient, as the rash, ignorant or unskilled departure from approved methods.⁹³

In 1935 a significant and enlightened decision by the Michigan Supreme Court in *Fortner v. Koch*⁹⁴ announced that human experimentation is necessary for medical purposes. The court removed clinical experimentation from the "outlaw status," authorizing medical investigation provided that the subjects knew of the experiment and consented to it, and so long as the experiment did not depart too radically from accepted treatment methods.⁹⁵ Prior to *Fortner*, experimentation was regarded as an intentional attack upon the patient and was treated in theory as battery. The gist of the cause of action was the absence of plaintiff's consent to the contact, rather than the wrongful intent of the defendant.⁹⁶ Liability was imposed for dangerous or inappropriate action to which the plaintiff had not consented. The *Fortner* court removed clinical research from those constraints and placed it in the context of "reasonableness." It anticipated that acceptable standards could be developed by examining the practice and procedure of clinical investigators serving as expert witnesses.⁹⁷

More recently, another court has also restricted physicians in their choice of experimental treatment for a patient. In *Kaimowitz v. Dep't of*

⁹² R. MORRIS & A. MORTIZ, DOCTOR AND PATIENT AND THE LAW 346-50 (1971); Cady, *Medical Malpractice: What About Experimentation?*, 6 ANNALS W. MED. & SURGERY 164 (1952); Curran, *supra* note 91, at 402-09; Ladimer, *Ethical and Legal Aspects of Medical Research on Human Beings*, 3 J. PUB. L. 467, 476-80 (1954).

⁹³ *Slater v. Baker*, 2 Wils. [K.B.] 359 (1767). *Slater* established the principle that if a standard therapy is available and the patient does not consent to experimental therapy, the physician is absolutely liable for any harm caused from use of the experimental therapy. *Id.* at 362. See L. REGAN, DOCTOR, PATIENT AND THE LAW 381 (2d ed. 1949). Brown v. Hughes, 94 Colo. 295, 30 P.2d 259 (1934); Langford v. Kosterlitz, 107 Col. App. 175, 290 P. 80 (1930); Board of Medical Registration and Examination of Indiana v. Kaadt, 225 Ind. 625, 76 N.E.2d 669 (1948); Carpenter v. Blake, 60 Barb. 488 (N.Y. 1871); Hodgson v. Bigelow, 335 Pa. 497, 7 A.2d 338 (1939).

⁹⁴ 272 Mich. 273, 261 N.W. 762 (1935).

⁹⁵ *Id.* at 282, 261 N.W. at 765.

⁹⁶ W. PROSSER, *supra* note 69, at 36.

⁹⁷ 272 Mich. 273, 261 N.W. 762 (1935). *Accord*, Karp v. Cooley, 493 F.2d 408 (1974) (holding that as to the issue of medical experimentation, the rules of medical malpractice should apply, *i.e.*, that expert testimony was required to support allegations that defendants had deviated from accepted norms of practice so as to be negligent or grossly negligent). See also Curran, *The First Mechanical Heart Transplant: Informed Consent and Experimentation*, 291 NEW ENGLAND J. MED. 1015 (1974).

Mental Health,⁹⁸ the court held that an involuntarily confined mental patient was unable to give informed consent to an experimental psychosurgical procedure.⁹⁹ The patient involved had been committed to a state hospital under Michigan's criminal sexual psychopath law. He and his parents signed consent forms allowing him to undergo the experimental procedure designed to control violent behavior in persons suffering from uncontrollable aggression.¹⁰⁰ Suit was brought by an attorney on behalf of the patient, and all others similarly situated, seeking a writ of habeas corpus on grounds that the patient was being illegally detained for experimental psychosurgery.¹⁰¹

Two issues were presented to the court. The first was whether an involuntarily detained mental patient is capable of giving informed consent to experimental psychosurgery which may alter thoughts, emotions or behavior. The second was whether, assuming the patient could consent, the State Department of Mental Health could conduct experimental psychosurgery on involuntarily confined mental patients in hospitals under its jurisdiction.¹⁰² The court answered the first question in the negative, and therefore did not reach the second.¹⁰³

The court identified three criteria for informed consent, which it ascertained from the Nuremberg standards: competence, knowledge, and voluntariness.¹⁰⁴ The court explained that competence "requires the ability of the subject to understand rationally the nature of the procedure, its risks, and other relevant information."¹⁰⁵ The patient's involuntary confinement diminished his capacity to give consent even if he understood the nature of the procedure.¹⁰⁶ In addition, the court stated that if the patient is incompetent to give consent to experimental psychosurgery, his guardian is likewise incompetent to give consent for him.¹⁰⁷

Knowledge of the benefits and hazards of the proposed surgery and difficulties in recuperation could not be acquired because, according to the court, medical science was not sufficiently advanced to state with certainty what relationship, if any, exists between the part of the brain

⁹⁸ 1 MENTAL DISABILITY L. REP. 147, summarized at 42 U.S.L.W. 2063 (Mich. Cir. Ct. 1973).

⁹⁹ *Id.* at 151.

¹⁰⁰ *Id.*

¹⁰¹ *Id.*

¹⁰² *Id.* at 147-48.

¹⁰³ *Id.* at 153.

¹⁰⁴ *Id.* at 150-51.

¹⁰⁵ *Id.* at 150.

¹⁰⁶ *Id.*

¹⁰⁷ *Id.*

proposed for surgery and the subject's subsequent behavior.¹⁰⁸ The court concluded that as psychosurgery is experimental and the benefits of the proposed procedure were uncertain at best,¹⁰⁹ the knowledge requirement of informed consent was not satisfied. Finally, the court evaluated the element of voluntariness and found that the patient, due to his involuntary confinement, could not exercise his power of free choice and therefore could not voluntarily choose to undergo psychosurgery.¹¹⁰

Kaimowitz is significant because it is the first judicial analysis of informed consent in the context of experimental psychosurgery.¹¹¹ For the first time, limitations were placed on physician experimenters using radical medical technologies as a last resort to control extreme behavioral problems.¹¹² *Kaimowitz* is also significant for its recognition of the individual's right to mental integrity as an essential aspect of the right to privacy.¹¹³

B. DEVELOPMENT OF FDA REGULATIONS

It is important to understand that regulation of human experimentation in the United States is controlled by two major agencies of the federal government, the Food and Drug Administration (FDA) and the Public Health Service-National Institutes of Health (PHS-NIH) complex. The purposes of these two agencies are entirely different, and their impact upon research has significant variations. The FDA is product-oriented. It is charged with regulation of pharmaceutical corporations and other business firms which engage in manufacture and distribution of medicinal drugs and cosmetics for profit. These enterprises are highly competitive, and the primary purpose of the agency is to protect the consumer by making sure that products are safe for the public and by protecting the public's rights during investigations to determine the efficacy of products. Exceptions to FDA regulations are allowed only in accordance with the exemptions established by statute,¹¹⁴ and controls are applied uniformly throughout the nation.

The National Institutes of Health (NIH), by contrast, is not a regulatory agency. Its responsibilities relate mainly to the support of a na-

¹⁰⁸ *Id.* at 148.

¹⁰⁹ *Id.* at 149.

¹¹⁰ *Id.* at 151.

¹¹¹ Note, *supra* note 31, at 953.

¹¹² Peters & Lee, *supra* note 31, at 383.

¹¹³ *Id.* at 390. The *Kaimowitz* decision has come under serious criticism. It may, in fact, hinder a patient's right to treatment. See Wexler, *Mental Health and the Movement Toward Voluntary Treatment*, 62 CAL. L. REV. 671 (1974). See generally G. ANNAS, L. GLANTZ & B. KATZ, *INFORMED CONSENT TO HUMAN EXPERIMENTATION* (1977); D. WEXLER, *MENTAL HEALTH LAW: MAJOR ISSUES* (1981).

¹¹⁴ 21 C.F.R. §§ 312.1-312.10 (1980).

tional program of health science research.¹¹⁵ NIH is a respected member of the scientific community, with which it shares philosophies and aspirations. Its own policy is to encourage academic freedom and creativity in research by its extramural project grants. The primary interest of NIH is in the best possible scientific results, and it considers the patient-subject a valuable partner in this endeavor. Instead of a confining and substantive regulatory program, NIH has developed a decentralized system of local institutional review committees which rely on ethical guidelines instead of specific regulations to protect the patient-subjects of the projects it supports. However, NIH assumes direct responsibility for protecting research subjects through its own system of central review of project applications.¹¹⁶ NIH has developed a system of law-producing mechanisms based upon enlightened and conscientious self-government by its investigators. In the early 1950s significant efforts to establish codes for human research were made in reaction to the principles announced in *Fortner v. Koch*.¹¹⁷ Despite those early attempts at codification and the impetus of Nuremberg and Helsinki, no comprehensive federal code for human experimentation was created.¹¹⁸

Amid the failure to take an affirmative stand on human experimentation, the world was shocked by the outbreak of infantile deformity in Western Europe in 1961 and 1962 as a result of the use of thalidomide by pregnant women. The tragedy took place while drug companies were being investigated by Senator Estes Kefauver's Subcommittee on Antitrust and Monopoly.¹¹⁹ When the request for permission to study Thalidomide as a new drug was withdrawn in March 1962, the FDA undertook to recall the drug. Although the FDA initially believed that only forty or fifty doctors in the United States had the drug for testing, it discovered that by August 1962, over 2100 kilograms of tablets had been distributed to some 1,231 investigators, who had prescribed the drug to

¹¹⁵ Curran, *supra* note 88, at 570-89.

¹¹⁶ *Id.* at 586-88.

¹¹⁷ In 1903, 1912, 1949 and 1957 the American Medical Association published revisions of its Code of Ethics, which governs the physician's conduct in relation to his patient and describes accepted attitudes toward clinical experimentation. In 1966 the A.M.A. approved the principles of human experimentation established by the World Medical Association in Helsinki in 1964 and added several regulations of its own, which may have influenced the early rules of conduct promulgated by the Food and Drug Administration and National Institutes of Health. *Id.* at 564-65.

¹¹⁸ In 1961, Dr. Louis G. Welt received responses from sixty-six university medical departments (out of eighty-six questioned) in the United States regarding an inquiry whether they had established some formal procedure for human experimentation. Only eight answered that some sort of "procedural document" dealing with potential problems in this area existed at their institution. Welt, *Reflections on the Problems of Human Experimentation*, 25 CONN. MED. 75, 77-78 (1961).

¹¹⁹ Hearings of this subcommittee had begun on December 7, 1959, and were in progress at the time of the Thalidomide tragedy.

19,822 patients, including some 3,760 women of child-bearing age.¹²⁰ None of this activity was unlawful, since the existing FDA statute¹²¹ (in force since 1938) merely required application for use of new drugs on the market and permitted their distribution for investigation to clinical investigators if the drug carried the label: "Caution—New Drug—Limited by federal law to investigational use." Equipped with this information on Thalidomide, the Kefauver hearings resulted in the Kefauver-Harris Bill, known as the Drug Amendments of 1962,¹²² which became the basis for the present FDA regulations.¹²³

Under the 1938 statute, the FDA required only that the drug manufacturers seek an investigational-use exemption to study a new drug.¹²⁴ Notice of actual shipments, information of research protocol or the qualifications, number or locations of investigators was kept by the FDA. However, because the agency was relatively limited in personnel and scope, it was forced to confine its activities largely to reviewing new drug applications before permitting them to enter the general market. The FDA's approach was the result of previous experience with public distribution of elixir-sulfanilamide which had led to requirements for testing drug toxicity on animals before marketing.¹²⁵

The Drug Amendments of 1962 radically changed the role of the FDA from the simple monitor of drug safety into the arbiter of value, quality and success in experimentation with drugs. The 1962 amendments required not only that drugs be safe for public consumption but also that there be "substantial evidence" of effective therapeutic value, supported by "well controlled investigation," including clinical studies, before release of the drug.¹²⁶ Drug advertising was controlled more strictly. Contraindications, precautions and harmful side effects were

¹²⁰ Lear, *The Unfinished Story of Thalidomide*, SATURDAY REV., Sept. 1, 1962, at 38. Fortunately the drug was never used extensively in the United States, largely because of withholding of approval by Dr. Frances O. Kelsey of the FDA's Bureau of Medicine.

¹²¹ Federal Food, Drug, and Cosmetic Act, ch. 675, 52 Stat. 1040 (1938).

¹²² Pub. L. No. 87-781, 76 Stat. 780 (1962) (codified in scattered sections of 21 U.S.C.).

¹²³ 21 C.F.R. §§ 310.3-310.304; 312.1-312.20; 314.235 (1980).

¹²⁴ Federal Food, Drug, and Cosmetic Act, ch. 675, § 505, 52 Stat. 1052 (1938).

¹²⁵ Jurow, *Government and Consumer Protection—Drugs*, 22 FOOD DRUG COSM. L.J. 593, 597 (1967). Introduction of sulfanilamide had resulted in cases of kidney shutdown secondary to use of the drug. This was the country's first experience with drug toxicity in an agent that had great therapeutic value. (Sulfa drugs predated penicillin and were the first successful systemic antibiotics capable of combatting deadly infections in humans). Since clinical observations quickly demonstrated that renal complications could be reduced by the simple expedient of alkalizing the patient with sodium bicarbonate or other suitable alkalis and by providing him with ample oral fluid intake, the importance of animal toxicity studies in spite of the urgent need for a drug became apparent. *Id.* at 595. Moreover, the requirement for such studies set the stage for Dr. Kelsey's fortuitous withholding of Thalidomide from the drug market.

¹²⁶ 21 U.S.C. § 355(d) (1976).

required on labels.¹²⁷ More stringent requirements for new drug applications were established. Comprehensive regulations on clinical testing of new drugs were formulated. These included keeping adequate records, reviewing the reports of all preclinical tests, such as animal tests that might justify clinical testing, and obtaining signed agreements from clinical investigators indicating that tests would be conducted under their personal supervision and that the drugs would be distributed to no one other than approved human subjects.¹²⁸

The drafters of the Drug Amendments of 1962, preoccupied with regulating the testing and marketing of drugs, overlooked the need for patient-subject consent. This requirement was added by amendment on the floor of the Senate.¹²⁹ Consent of the subject was made mandatory, leaving the FDA no discretion in its application of the statute.¹³⁰ There were, however, two exceptional situations in which consent was not required: (1) if consent was not feasible in the opinion of the investigator (for example, in an unconscious patient), and (2) if consent was contrary to the best interests of the subject.¹³¹

FDA regulations to implement the Drug Amendments of 1962 required notification of any interstate shipment of investigational drugs and detailed information on preclinical testing.¹³² The FDA also reserved the right to require the sponsor of the tests on investigational drugs to submit complete clinical data and to withhold further testing if the preclinical testing data did not support the safety or efficacy of the drug.¹³³ Moreover, the sponsor could also be required to discontinue new drug shipments if any investigator repeatedly or deliberately failed to maintain or make available his records on or reports of investigations.¹³⁴

The FDA regulations further established three phases of clinical investigation.¹³⁵ Phases I and II deal with clinical-pharmacological evaluation of drugs on humans. A general outline is required identifying the investigator(s), the hospital or research facility where the study is done, the expert committee or panels to be used for supervision, the maximum number of subjects needed and the estimated duration of the pharmacological studies.¹³⁶ These regulations provide adequate safeguards

¹²⁷ *Id.*

¹²⁸ *Id.* § 355(i) (1976).

¹²⁹ 108 CONG. REC. 17364, 17391, 17395 (1962) (remarks of Sen. Javits).

¹³⁰ 21 U.S.C. § 355(i) (1976).

¹³¹ *Id.*

¹³² 21 C.F.R. §§ 310.3-310.304; 312.1-312.20; 314.1-314.235 (1980).

¹³³ *Id.* § 312.1(a)(2) (1980).

¹³⁴ *Id.* § 312.1(a)(8) (1980).

¹³⁵ *Id.* § 312.1(a)(2) (1980).

¹³⁶ *Id.*

against ethical problems even though this is not the regulation's primary purpose. Furthermore, the regulations no longer allow the sponsor to unduly prolong distribution of drugs for investigational use. Once the initial period for distribution has expired investigation must either be discontinued or a new drug application must be filed.¹³⁷

In the Phase III testing, which is the final clinical testing before marketing, the sponsor must submit a protocol developed on the basis of the facts accumulated in the earlier phases, including completed animal studies.¹³⁸ For compliance with this phase, the following data are required: planned clinical observations, specific laboratory tests, names and addresses of investigators, the approximate number of subjects, and the estimated duration of clinical trials and intervals. The clinical trials cannot exceed one year. Phase III testing usually requires more than one independent investigator, and mandates that each investigator keep adequate records on each subject treated. A "full statement" is necessary on any adverse effect, together with a statement of opinion as to whether or not such an effect is attributable to the drug under study.¹³⁹ If the adverse effect of a drug is "alarming," the sponsor must be informed immediately, and he must then report to the FDA. The sponsor is also required to report discontinuation of a drug study along with the reasons for doing so.¹⁴⁰ If Phase III studies proceed satisfactorily, periodic reports to the FDA are required.¹⁴¹ Investigational use cannot be unduly prolonged without requiring a new drug application.¹⁴²

The requirement for patient-subject consent became a matter of specific regulation and definition. The term "informed consent" was eliminated in order to avoid confusion with the term as it is used in medical malpractice. The use is inapplicable in studies of new experimental drugs, the effects of which are not entirely known or predictable. In formulating its definition, the FDA used the concepts of Nuremberg and Helsinki, in addition to the rules formulated by the Ethical Guidelines for Clinical Research and adopted by the American Medical Association on November 30, 1966.¹⁴³ The definition of consent in the regulations is as follows:

'Consent'. . . means that the person involved has legal consent, is so situ-

¹³⁷ *Id.* § 312.1(a)(4) (1980).

¹³⁸ *Id.* § 312.1(a)(2) (1980).

¹³⁹ *Id.*

¹⁴⁰ *Id.* § 312.1(a)(6) (1980). Such findings include significant hazards, side effects, contraindications, and precautions pertinent to the safety of the drug.

¹⁴¹ *Id.* § 312.1(a)(5) (1980).

¹⁴² *Id.*

¹⁴³ Curran, *supra* note 88, at 564-65. See also notes 58-67 & accompanying text *supra* for World Medical Association, Declaration of Helsinki and American Medical Association Ethical Guidelines for Clinical Investigation (1966).

ated as to be able to exercise free power of choice, and is provided with a fair explanation of all material information concerning the administration of the investigational drug, or his possible use as a control, as to enable him to make an understanding decision as to his willingness to receive said investigational drug. This latter element requires that before the acceptance of an affirmative decision by such person, the investigator should make known to him the nature, duration and purpose of the administration of said investigational drug; the method and means by which it is to be administered, all inconveniences and hazards reasonably to be expected, including the fact, where applicable, that the person may be used as a control; the existence of alternative forms of therapy, if any; and the effects upon his health or person that may possibly come from the administration of the investigational drug. Said patient's consent shall be obtained in writing by the investigator.¹⁴⁴

Time and usage have resulted in some slight changes in the wording of this definition,¹⁴⁵ but the effect and implications remain essentially unchanged. Written consent of Phase III subjects has been relaxed, provided the investigator certifies on the patient's medical record that consent requirements have been fulfilled.¹⁴⁶ The definition of consent was not intended to eliminate the "double blind" study,¹⁴⁷ but it clearly envisions informing the subject that he may be used as a control rather than as a subject who actually receives the investigational

¹⁴⁴ 21 C.F.R. § 310.102(h) (1980).

¹⁴⁵ In 32 Fed. Reg. 3994 (1967) (codified in 21 C.F.R. § 130), consent is defined as follows:

'Consent' means that the person involved has legal capacity to give consent, is so situated as to be able to exercise free power of choice, and is provided with a fair explanation of pertinent information concerning the investigational drug, and/or his possible use as a control, as to enable him to make a decision on his willingness to receive said investigational drug. This latter element means that before acceptance of an affirmative decision by such person the investigator should carefully consider and make known to him (taking into consideration such person's wellbeing and his ability to understand) the nature, expected duration, and purpose of the administration of said investigational drug; the method and means by which it is to be administered; the hazards involved; the existence of alternative forms of therapy, if any; and the beneficial effects upon his health or person that may possibly come from the administration of the investigational drug.

When consent is necessary under the rules set forth in this section, the consent of persons receiving an investigational new drug in Phase 1 and Phase 2 investigations (or their representatives) shall be in writing. When consent is necessary under such rules in Phase 3 investigations, it is the responsibility of the investigators, taking into consideration the physical and mental state of the patient, to decide when it is necessary or preferable to obtain consent in other than written form. When such written consent is not obtained, the investigator must obtain oral consent and record that fact in the medical record of the person receiving the drug.

¹⁴⁶ *Id.*

¹⁴⁷ "Double blind" studies are done to insure accuracy of results. Neither the investigator nor the patient knows whether the patient is receiving the experimental drug or a placebo. After the drug has been administered and observations taken, someone, preferably a neutral person, determines who has received the new drug and who has received the placebo. This procedure leads to relatively accurate assessment of the experimental new drug. Bowker, *supra* note 1, at 164-65. See also Weinstein, *Allocation of Subjects in Medical Experiments*, 291 NEW ENGLAND J. MED. 1278, 1279 (1974).

drug. The two exceptions,¹⁴⁸ the comatose patient and the patient who does not understand or whose best interests preclude obtaining consent, have been increasingly interpreted to mean that these patients should be removed from investigational studies, unless their condition justifies administration of such drugs as a final therapeutic life-saving measure. Research in seriously ill or terminal patients is not encouraged.¹⁴⁹ These statutory regulations on drug investigation are applied universally.

C. DEVELOPMENT OF NIH GUIDELINES AND CONTROL SYSTEMS

The National Institutes of Health began with the establishment of the National Cancer Institute in 1937 and with it the beginning of extramural awards to qualified researchers in the United States outside of NIH. Both NIH and the extramural grants for research and education grew in number and importance until, by 1979, some \$3.2 billion were appropriated for research activities and grant support.¹⁵⁰ The NIH is not a regulatory agency. It conducts its own research programs and supports other responsible institutions and investigators in order to maintain a national program of health science research. One of the most important contributions of NIH is its establishment of a unique system of ethical guidelines for the use of human subjects in clinical investigations.

NIH is staffed at all levels by experienced scientists and administrators and has become an integral part of the scientific community. It has always respected the scientist's insistence upon intellectual freedom and to this end has traditionally not interfered with institutional policies concerning faculty appointments, staff salaries or terms of employment. Decisions on publications of findings are left to the principal investigators, and much freedom is allowed for changes in research design. How-

¹⁴⁸ Drug Amendments of 1962, 21 § U.S.C. § 355(i) (1976). See also 21 C.F.R. § 310.102 (1980).

¹⁴⁹ See generally P. RAMSEY, *supra* note 79; Martin, *supra* note 75.

¹⁵⁰ Fredrickson, *supra* note 45, at 512. In addition to the National Cancer Institute, the Division of Research Grants was established in 1946, the National Heart Institute and the National Institute of Dental Research in 1948, the Experimental Biology and Medicine Institute and the National Institute of Dental Research in 1948, the National Institute of Mental Health (which was merged with the Mental Hygiene Program of the Public Health Service) in 1949, the National Institute of Neurological Diseases and Blindness and the National Institute of Arthritis and Metabolic Disease in 1950; the Clinical Center of NIH in 1953, the Division of General Medical Sciences in 1963, and the National Eye Institute and the John E. Fogarty International Center for Advanced Study in 1968. Curran, *supra* note 88, at 570-71.

The NIH medical research budget increased from \$17 million in 1948 to \$803 million in 1967 and rose to \$1.2 billion in 1968. DIVISION OF RESEARCH GRANTS, NIH, BASIC DATA RELATING TO THE NATIONAL INSTITUTES OF HEALTH 6 (1968). In 1977 actual funds appropriated for NIH amounted to \$2.5 billion, and in 1979, the proposed budget was \$2.9 billion. UNITED STATES GOVERNMENT, THE BUDGET, Fiscal Year 1979, 342.

ever, NIH bears the ultimate responsibility for ensuring competent, effective research and for protecting the rights of human subjects.

Concern by NIH for ethical standards in human experimentation began in 1953 when the Clinical Center in Bethesda, Maryland, set forth a set of principles and procedures. At first, those requirements were met formally, but as patient-subjects came to be regarded as integral members of the research team, they were as fully informed as possible of the investigations contemplated, particularly as to potential hazards.¹⁵¹ If an unusual risk was involved, the patient-subject was asked to submit a written consent or to indicate in a separate memorandum his understanding of the procedure and its purpose, his understanding of potential dangers to himself and his willingness to participate in the investigation.¹⁵²

Because of the interest generated by NIH policies and the experience at the Clinical Center, an ad hoc study group was formed in 1964 to consider in greater depth the advisability of applying ethical guidelines to the extramural grants supported by NIH. This committee forwarded a report to the Surgeon General in January 1965, with four recommendations:

1. That an appropriate inter-professional group should be encouraged to formulate a statement of principles relating to moral and ethical aspects and activities.
2. That there is a need for factual information concerning actual research procedures and activities.
3. That the NIH should consider providing advice, at the request of grantees, concerning ethical problems and risk-reducing practices in clinical research.
4. That research grant documentation relating to the use of human subjects in clinical investigation should be identified for special consideration throughout the NIH-PHS review process.¹⁵³

These ethical guidelines were also considered by the National Advisory Health Council when it adopted a resolution in December 1965, requiring that “. . . 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 individuals involved . . .”¹⁵⁴

On February 8, 1966, the Surgeon General issued the following policy statement:

¹⁵¹ Sessoms, *Guiding Principles in Medical Research Involving Humans*, 32 HOSPITALS 44, 64 (1958).

¹⁵² Curran, *supra* note 88, at 575.

¹⁵³ *Id.* at 576.

¹⁵⁴ *Id.*

No new, renewal or continuation research or research training grant in support of clinical research and investigation involving human beings shall be awarded by the Public Health Service unless the grantee has indicated in the application the manner in which the grantee institution will provide prior review of the judgment of the principal investigator or program director by a committee of his institutional associates. This review should assure an independent determination: (1) of the rights and welfare of the individual or individuals involved, (2) of the appropriateness of the methods used to secure informed consent, and (3) of the risks and potential medical benefits of the investigation. A description of the committee of the associates who will provide the review shall be included in the application.¹⁵⁵

The Surgeon General's policy was first applied only to research and research training agents but soon spread to almost all other NIH-supported extramural projects. Initially each grant was required to have the description of an appropriate local institutional committee responsible for overseeing the principal investigator. Because this requirement increased "paper work," it was revoked and replaced by one in which an institution filed an assurance, agreement or compliance only once and indicated that the review committee would be responsible for overseeing all grant applications received from investigators at that particular institution. This assurance also carried a description of the review committee or committees in the institution and of the methods used to ensure compliance with the advice of the review committee. Any changes in the committees or their policies had to be reported and reapproved.

In December 1966, the Surgeon General made another policy change relating to research in the behavioral and social sciences. This policy made the grantee institution responsible for ensuring that the investigations are "in accordance with the laws of the community in which the investigations are conducted. . . ."¹⁵⁶

The establishment of local institutional review committees had a profound effect on the participating institutions. Doubt as to the importance which NIH attached to the moral and ethical considerations of research in human subjects all but vanished. Those concerns were addressed by the fulfillment of three needs: (1) to protect the rights and welfare of subjects by reviewing the judgment of the investigator and enforcing compliance with the Committee's recommendations, (2) to obtain "informed consent" from the experimental subject, and (3) to assess the risks against the potential benefits of the investigation before granting approval.¹⁵⁷ The third criterion had a salutary effect because the number of "problem projects"—those posing serious hazards to experimental subjects—fell significantly.¹⁵⁸

Although NIH did not require that the committees review the ap-

¹⁵⁵ *Id.* at 577.

¹⁵⁶ *Id.*

¹⁵⁷ *Id.* at 578.

¹⁵⁸ *Id.* at 579-80.

plications before submission to the NIH review and approval system, this became the standard practice. Thus, when final approval was granted to a project, it had first cleared the local review committee and had received final approval at the NIH level. The requirement that ultimate responsibility for proper research rest with NIH was fulfilled without having to resort to the cumbersome system of frequent site visits and re-evaluation of projects after approval by local committees. Finally, the existence of local review committees charged with responsibility for overseeing NIH projects in a given institution diminished the authority of other investigators. In time, these investigators sought approval of their projects even though this was not required of research which did not receive support from NIH.¹⁵⁹

Other benefits from the NIH ethical guidelines have accrued or are expected. The concept of "informed consent" has been retained by NIH policy-makers despite the connotation derived from medical malpractice litigation.¹⁶⁰ The concept remains in order to protect a lay person who may not be fully aware of all the ramifications of the research project in which he plans to participate despite conscientious explanations to him. Also, many local committees weigh for themselves the risk-benefit aspects of a project for the patient and may reject the project for him despite his willingness to accept the risks involved. While the committee is thereby subjected to added legal hazards, this procedure affords the overzealous patient an added measure of protection. Although most local review committees continued to be "parochial" in the sense that they are composed of other scientists who "understand" one another,¹⁶¹ many now include other professionals and thus have broadened the scope of the local review process.¹⁶² Even laymen are beginning to be introduced into the review committees to present a totally non-profes-

¹⁵⁹ *Id.* In view of the indefinite nature of the concepts and terminology concerning the safeguarding of the patient-subject's rights and safety under experimentation guidelines of the Nuremberg and Helsinki codes and the FDA and NIH guidelines, the responsibility of local review committees becomes a matter of prime importance. Since it is doubtful that the concepts and terminology can be more explicitly defined and still be applicable to any given situation, these local review committees must interpret codes and guidelines in such a manner as to protect the patient-subject's rights without stifling scientific and medical investigation.

¹⁶⁰ See note 70 *supra*.

¹⁶¹ Of 142 local review committees surveyed by the NIH in 1968, 104 (or 73 percent) were limited to institutional peer groups. Eighteen also included attorneys; sixteen included lay associates and one included both attorneys and clergy. Eleven had broad interdisciplinary representation in which the scientific peer group was in a minority. Curran, *supra* note 88, at 583.

¹⁶² There are definite advantages to inclusion of attorneys, philosophers, clergymen, and local citizens in the deliberations of the review committees. Attorneys can provide special knowledge in local laws and procedure. Philosophers and clergymen have a serious concern with ethical issues and human values and may contribute attitudes and convictions not considered by the scientists. Other professionals, businessmen and laymen can play an important

sional perspective.¹⁶³

Local review committees represent an effective approach to the development of a kind of common law precedent in the field of human experimentation.¹⁶⁴ However, to harvest the benefits of the experience accumulated by local review committees, a system for sharing relevant experiences must be developed. Major difficulties exist because of problems related to confidentiality and privacy¹⁶⁵ and the need to protect the reputation and integrity of researchers, subjects and review panels. NIH and local review committees must exchange views not only on their own projects but also about new moral and ethical issues in human research. Some success has been achieved,¹⁶⁶ but more of the imaginative administration that led to the founding of local review committees is needed.

D. ADDITIONAL LEGISLATION REGULATING HUMAN EXPERIMENTATION AND/OR REVIEW PROCEDURES

The Social Security Act Amendments of 1972¹⁶⁷ are the first in a series of more recent legislative measures designed to regulate human experimentation, review procedures or both. This statute creates another review system, the Professional Standards Review Organization (PSRO), whose purpose is to promote:

the effective, efficient and economical delivery of health care services of proper quality . . . to assure, through the application of suitable procedures of review, that the service for which payment may be made under the Social Security Act will conform to appropriate professional standards for the provision of health care. . . .¹⁶⁸

The PSRO has the responsibility of reviewing all health care services provided under the Social Security Act. Thus, it exerts a significant influence on the therapeutic relationship. Combined with other provisions which stress economical treatment of patients¹⁶⁹ and restricted ad-

role in areas concerning community responsibility. Moore, *Ethical Boundaries in Initial Clinical Trials*, in EXPERIMENTATION WITH HUMAN SUBJECTS, *supra* note 38, at 502-03.

¹⁶³ See generally Holman & Dutton, *A Case for Public Participation in Science Policy Formation and Practice*, 51 S. CAL. L. REV. 1505 (1978); Lappé & Martin, *The Place of the Public in the Conduct of Science*, 51 S. CAL. L. REV. 1535 (1978).

¹⁶⁴ See, e.g., *Fortner v. Koch*, 272 Mich. 273, 261 N.W. 762 (1935).

¹⁶⁵ See Gordon, *Issues in Human Experimentation*, 89 ANNALS INTERNAL MED. 846 (1978). For a discussion of confidentiality in research on human subjects, see generally R. BORUCH & J. CECIL, *ASSURING THE CONFIDENTIALITY OF SOCIAL RESEARCH DATA* (1979).

¹⁶⁶ See notes 176-206 & accompanying text *infra*.

¹⁶⁷ Pub. L. No. 92-603, 86 Stat. 1329 (1972).

¹⁶⁸ *Id.* § 1151.

¹⁶⁹ This section provides:

mission to health care facilities, especially those for inpatients,¹⁷⁰ the PSRO system is capable of controlling human experimentation performed in a therapeutic relationship. PSRO control is needed because the type of treatment, the admission to inpatient health facilities, the length of stay¹⁷¹ and economic dictates may erode the traditional therapeutic doctor-patient relationship in favor of increased experimentation. The clinical research aspect of human experimentation may also be affected by the PSRO system since it may utilize or influence local peer review committees established to review health care and clinical investigations at health care institutions.¹⁷²

. . . [P]ayment for such services will be made

(1) only when and, to the extent medically necessary, as determined in the exercise of reasonable limits of professional discretion; and

(2) in the case of services provided by a hospital or other health care facility on an inpatient basis, only when and for such period as such services cannot, consistent with professionally recognized health care standards, effectively be provided on an outpatient basis or more economically in an inpatient health care facility of a different type, as determined in the exercise of reasonable limits of professional discretion.

Id.

¹⁷⁰ This section provides:

Each Professional Standards Review Organization shall have the authority to determine, in advance, in case of —

(A) any elective admission to a hospital, or other health care facility, or

(B) any other health care service which will consist of extended or costly courses of treatment,

whether such service, if provided, or if provided by a particular health care practitioner or by a particular hospital or other health care facility, organization, or agency, would meet the criteria specified in clauses (A) and (C) of paragraph (1).

Id. § 1155(a)(2).

¹⁷¹ This section provides:

Each Professional Standards Review Organization shall—

(A) in accordance with regulations of the Secretary, specify the appropriate points in time after the admission of a patient for inpatient care in a health care institution, at which the physician attending such patient shall execute a certification stating that further inpatient care in such institution will be medically necessary effectively [*sic*] to meet the health care need of such patient; and

(B) require that there be included in any such certification with respect to any patient such information as may be necessary to enable such organization properly to evaluate the medical necessity of the further institutional health care recommended by the physician executing such certification.

(2) The points in time at which any such certification will be required (usually, not later than the 50th percentile of lengths-of-stay for patients in similar age groups with similar diagnoses)

Id. § 1156(d).

¹⁷² Each Professional Standards Review Organization shall utilize the services of, and accept the findings of, the review committees of a hospital or other operating health care facility or organization located in the area served by such organization, but only when and only to the extent and only for such time that such committees in such hospital or other operating health care facility or organization have demonstrated to the satisfaction of such organization their capacity effectively and in timely fashion to review activities in such hospital or other operating health care facility or organization (including the medical necessity of admissions, types and extent of services ordered, and length of stay) so as to aid in accomplishing the purposes and responsibilities described in subsection (a)(1) except where the Secretary disapproves, for good cause, such acceptance.

Id. § 1155(e)(1).

A more recent statute is the National Research Service Award Act of 1974 (NRA).¹⁷³ The express purpose of this statute is to ensure continued excellence in biomedical and behavioral research and to provide for protection of human subjects involved in such research. To achieve continued excellence in research, the Act authorizes the Secretary of the Department of Health and Human Services (HHS) to award grants for research and training in matters relating to the cause, diagnosis, prevention and treatment of disease or other health problems.¹⁷⁴ Awards and grants under the Act are subject to review and approval by advisory councils of NIH and the Alcohol, Drug Abuse and Mental Health Administration.¹⁷⁵

The NRA also provides for creation of a commission known as the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.¹⁷⁶ The Commission was charged with (1) conducting a comprehensive investigation to ascertain the ethical principles which underlie the conduct of biomedical and behavioral research, (2) developing guidelines to govern the conduct of such research, and (3) making recommendations to the Secretary of HHS regarding proper administrative action to apply such guidelines.¹⁷⁷ In carrying out its duties, the Commission was to consider the following matters:

- (i) The boundaries between biomedical or behavioral research involving human subjects and the accepted and routine practice of medicine.
- (ii) The role of assessment of risk-benefit criteria in the determination of the appropriateness of research involving human subjects.
- (iii) Appropriate guidelines for the selection of human subjects for participation in biomedical and behavioral research.
- (iv) The nature and definition of informed consent in various research settings.
- (v) Mechanisms for evaluating and monitoring the performance of Institutional Review Boards . . . and appropriate enforcement mechanisms for carrying out their decision.¹⁷⁸

The Commission was also responsible for identifying the requirements necessary for the informed consent of children, prisoners and the institutionalized mentally infirm before they can participate in human experimentation. On the basis of these investigations, it was to make

¹⁷³ Pub. L. No. 93-348, 88 Stat. 342 (1974).

¹⁷⁴ *Id.* § 472.

¹⁷⁵ *Id.* § 472(b)(2).

¹⁷⁶ *Id.* § 201(a) and (b). For a detailed discussion of the related human subjects protection committee as the principle legal mechanism for assuring protection of the rights and welfare of human subjects, see DuVal, *The Human Subjects Protection Committee: An Experiment in Decentralized Federal Regulation*, 1979 AM. BAR FOUNDATION RESEARCH J. 571.

¹⁷⁷ Pub. L. No. 93-348, § 202(a)(1)(A), 88 Stat. 342 (1974).

¹⁷⁸ *Id.* § 202(a)(1)(B).

recommendations to the Secretary which would assure that research conducted or supported under programs administered by HHS complied with the Commission's requirements for informed consent.¹⁷⁹ In addition, it was to conduct a study to determine if a mechanism was needed to protect human subjects in research not regulated by HHS and to make appropriate recommendations to Congress.¹⁸⁰ The Commission was also to conduct an investigation into research on living fetuses and into the use of psychosurgery and in both cases to recommend to the Secretary any policies defining the circumstances under which such research may be conducted or supported.¹⁸¹ Finally, it was to undertake a comprehensive study of the ethical, social and legal implications of human experimentation. The study was to include the following:

- (1) an analysis and evaluation of scientific and technological advances in past, present, and projected biomedical and behavioral research and services;
- (2) an analysis and evaluation of the implications of such advances, both for individuals and for society;
- (3) an analysis and evaluation of laws and moral and ethical principles governing the use of technology in medical practice;
- (4) an analysis and evaluation of public understanding of and attitudes toward such implications and laws and principles; and
- (5) an analysis and evaluation of implications for public policy of such findings as are made by the Commission with respect to advance in biomedical and behavioral research and technology and public attitudes toward such advances.¹⁸²

The NRA also creates a National Advisory Council for the Protection of Subjects of Biomedical and Behavioral Research.¹⁸³ Council members are selected from a variety of professional and academic backgrounds, but three members must have been engaged in human experimentation.¹⁸⁴ The Council's duties include attention to all aspects of research in human subjects and review of HHS policies and regulations to determine their effectiveness in gaining compliance with "the basic ethical principles which should underlie the conduct of such research. . . ." ¹⁸⁵ The Council is then to make appropriate recommendations. Moreover, the NRA establishes an Institutional Review Board,¹⁸⁶ under which any "entity" applying under the Act for a grant for research involving human subjects must demonstrate that it has estab-

¹⁷⁹ *Id.* § 202(a)(2).

¹⁸⁰ *Id.* § 202(a)(3).

¹⁸¹ *Id.* § 202(b) and (c).

¹⁸² *Id.* § 203.

¹⁸³ *Id.* § 211.

¹⁸⁴ *Id.*

¹⁸⁵ *Id.* § 211(a).

¹⁸⁶ *Id.* § 212(a).

lished a board to review such research in order to protect the rights of the subjects.¹⁸⁷ Finally, a limitation is placed by the NRA on research such that HHS may not conduct or support research on a living human fetus before or after an induced abortion except to ensure the survival of the fetus.¹⁸⁸

Upon completion of its investigation, the Commission created in accordance with the NRA submitted several recommendations.¹⁸⁹ First, it recommended that therapeutic research involving fetuses and pregnant women may be conducted and supported, provided that certain conventional ethical review procedures and safeguards are followed. Secondly, nontherapeutic research must pose "minimal or no risk on the fetus *in utero*" and must be aimed at development of important biomedical knowledge that is not obtainable by alternative means. Third, nontherapeutic research in anticipation of abortion must be approved by a national ethical review body if the research presents special problems.¹⁹⁰ Concerning research using prisoners as subjects, the Commission recommended that a national ethical review body must first be consulted. In addition the research must fulfill an important social and scientific need, and the reasons for involving prisoners must be compelling. Fourth, the conduct of the research should be characterized by a high degree of voluntariness on the part of participants, and institutions should express their willingness to be involved. Finally, with respect to psychosurgical procedures, the Commission provisionally adopted the position that such procedures could be supported and performed under carefully defined conditions. The Commission would approve efforts to evaluate the safety and efficacy of specific psychosurgical operations, provided that surgical competence, well-designed evaluations of outcome and adequate protection of patients' rights are assured. Institutional review boards must also give approval.

The Commission's recommendations are relatively strict regarding prisoners, relatively permissive regarding psychosurgical procedures and intermediate regarding fetuses. By law the Commission's recommenda-

¹⁸⁷ *Id.*

¹⁸⁸ *Id.* § 213. See generally Brock, *supra* note 81.

¹⁸⁹ U.S. NAT'L COMM'N FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, HEW INSTITUTIONAL REVIEW BOARDS (1978) (Dep't of H.E.W. Pub. No. (05) 78-0008). Research in children and the institutionalized mentally infirm are still on the Commission's agenda. *Id.* For a discussion of the changes in legal relations which have taken place between the federal government and research institutions and investigators as a result of the development of institutional review boards, see Robertson, *The Law of Institutional Review Boards*, 26 U.C.L.A. L. REV. 484 (1979).

¹⁹⁰ See also Curran, *Experimentation Becomes a Crime: Fetal Research in Massachusetts*, 292 NEW ENGLAND J. MED. 300 (1975) (discussing statute intended to prohibit experimentation on live human fetuses, within womb or outside, but with certain exceptions).

tions must either be adopted by the Secretary of HHS or reasons must be given for rejection.

Regulations also have been published by the Secretary of HHS for protection of human subjects which are applicable to all HHS supported research.¹⁹¹ Like the NIH-local peer review model, the primary responsibility for safeguarding the rights of subjects is placed on the institutions which receive HHS funds. HHS requires that Institutional Review Boards (IRB) be established to approve research activities.¹⁹² The review boards are to consider risk-benefit questions, adequacy of informed consent and continuing review.¹⁹³ In addition, recipients of HHS funds for research which involves risk to human subjects are required to submit written assurance that they will comply with HHS guidelines.¹⁹⁴ These regulations also provide for additional protections pertaining to research involving fetuses, pregnant women and human *in vitro* fertilization.¹⁹⁵ To implement those protections the Secretary is authorized to establish Ethical Advisory Boards (EAB). The mission of the EAB is to give advice as to whether particular research projects are consistent with the ethical guidelines of HHS.¹⁹⁶ It is further provided that no application involving human *in vitro* fertilization may be funded by HHS until the EAB has reviewed and given advice as to acceptability from an ethical standpoint.¹⁹⁷

The Institutional Review Boards are charged with additional duties concerning research involving fetuses, pregnant women and *in vitro* fertilization under the HHS regulations.¹⁹⁸ The IRB must determine that adequate consideration has been given to the manner of selecting subjects and that the applicant has adequately provided for the monitoring of the informed consent process.¹⁹⁹ The regulations further require that animal studies and studies on nonpregnant individuals be completed before any activity to which the regulations apply may be undertaken, except to meet the health needs of the mother or fetus or where the risk to the fetus is minimal.²⁰⁰ Investigators in such activities are required to refrain entirely from decisions to abort or to determine the viability of the fetus at the time of abortion.²⁰¹ In addition, preg-

¹⁹¹ 45 C.F.R. §§ 46.101-46.306 (1980). These regulations were enacted pursuant to 5 U.S.C. § 301 (1975). See also Bryant, *supra* note 58, at 25.

¹⁹² 45 C.F.R. § 46.102(a) (1980).

¹⁹³ *Id.* § 46.102(b).

¹⁹⁴ *Id.* § 46.104.

¹⁹⁵ *Id.* § 46.201.

¹⁹⁶ *Id.* § 46.204(a).

¹⁹⁷ *Id.* § 46.204(d).

¹⁹⁸ *Id.* § 46.205.

¹⁹⁹ *Id.* § 46.205(a)(2).

²⁰⁰ *Id.* § 46.206(a).

²⁰¹ *Id.* § 46.206(a)(3)-(4).

nant women may not be involved in HHS supported studies unless the purpose is to meet the health needs of the mother, the risk to the fetus is minimal and informed consent has been obtained regarding possible impact on the fetus.²⁰² Although, a fetus *in utero* can be a research subject, the risk must be minimal, the purpose of the research must be to meet its health needs, or the research must be directed at gaining important biomedical knowledge not otherwise obtainable.²⁰³ However, the parents must give their informed consent.²⁰⁴ Finally, no fetus *ex utero* may be a subject unless it is viable, as defined by regulation, there is no added risk or the study involves important knowledge that cannot be obtained by other means.²⁰⁵ However, a nonviable fetus may be a research subject if (1) its vital functions are not artificially maintained, (2) experimental activities which would themselves terminate the vital functions of the fetus are not used and (3) the purpose of the activity is to develop important biomedical knowledge not otherwise obtainable.²⁰⁶

In general, viable fetuses and pregnant women enjoy relatively strict protections under the HHS regulations, but those protections yield more easily in the case of nonviable fetuses, which are more likely to be aborted.²⁰⁷ Even though investigators are required to refrain from decisions to abort or to determine viability, non-investigator physicians are not so prohibited. Working in concert with investigators, they may furnish experimental subjects and thereby circumvent the HHS regulation, thus sacrificing the right of aborted fetuses to be free from experimentation. Legalization of abortion was never contemplated for this purpose.²⁰⁸

The FDA also has continued to focus its attention on human experimentation by issuing guidelines for clinical evaluation of drugs and their impact upon the development of new anti-infective agents.²⁰⁹ Those guidelines contain general principles and specific advice. They are intended to facilitate the planning and conduct of research without unduly confining innovation or technological advancement. They are recommendations of desirable approaches and appropriate methods for

²⁰² *Id.* § 46.207.

²⁰³ *Id.* § 46.208(a).

²⁰⁴ *Id.* § 46.208(b).

²⁰⁵ *Id.* § 46.209(a). See also note 74 & accompanying text *supra*.

²⁰⁶ 45 C.F.R. § 46.209(a)(1)-(2).

²⁰⁷ See P. RAMSEY, *supra* note 79, at 37-40; Martin, *supra* note 75, at 568-69; notes 79-81 & accompanying text *supra*.

²⁰⁸ See *Roe v. Wade*, 410 U.S. 113 (balancing required between pregnant woman's right to obtain safe, inexpensive, and nonintrusive abortion and right of state to protect maternal health and fetal life). See also Powledge & Fletcher, *Guidelines for the Ethical, Social and Legal Issues in Prenatal Diagnosis*, 300 NEW ENGLAND J. MED. 168, 170-71 (1979).

²⁰⁹ Crout, *Guidelines of the Food and Drug Administration for Study of New Drugs in Human Subjects*, 89 ANNALS INTERNAL MED. 832 (1978).

conduct of clinical research on drugs in humans.²¹⁰ Under FDA regulations, all clinical guidelines represent formal agency advice. Research initiated in good faith under the guidelines will be accepted for review purposes unless a guideline is formally rescinded for valid health reasons.²¹¹ One such FDA guideline relates to general evaluation of drugs in humans.²¹² Another considers evaluation of drugs in infants and children.²¹³ The former contains an introductory section dealing with principles of review by the Institutional Review Board, informed consent and design of controlled trials. It also states objectives, provides for preclinical testing of drugs and provides for testing during the investigational phases²¹⁴ for determining drug efficacy.

The expanding field of human experimentation is viewed with concern in the United States. Various legislative responses have been fashioned in an effort to impart order to this expansion so that necessary growth of scientific knowledge will continue. Legislation also has sought to counterbalance the effect of the growth in human experimentation by protecting subjects who might otherwise suffer injury in the experimental process.

VI. INTERNATIONAL AND COMPARATIVE ASPECTS OF HUMAN EXPERIMENTATION

A. PAST INTERNATIONAL EXPERIENCE AND COOPERATION

In order to establish a practical and desirable foundation for international control of human experimentation, it is necessary to examine the attitudes of other nations, past international cooperation and the efforts of international scientific, medical, and other professional organizations. Through such analysis a valid determination of the need for and success of a proposal for international cooperation and commitment can be made. Regardless of the public concern and medical and scientific commitment that seems to prevail in the United States, there can be little hope for effective international control if such attitudes do not exist internationally.

The scant interest in regulating human experimentation in the United States prior to 1960 existed throughout the world until the revelations at Nuremberg. Few countries had enacted regulations or developed legal precedent, nor was there an international medical association

²¹⁰ *Id.*

²¹¹ 21 C.F.R. § 10.90(b) (1980).

²¹² FOOD & DRUG ADMIN., GENERAL CONSIDERATIONS FOR THE CLINICAL EVALUATION OF DRUGS IN INFANTS AND CHILDREN (1977) (Dep't of HEW Pub. No. 77-3040).

²¹³ *Id.* (Dep't of HEW Pub. No. 77-3041).

²¹⁴ *See* notes 135-49 & accompanying text *supra*.

to establish guidelines based on a consensus of world opinion. Doctors and scientific investigators were forced to rely upon their own moral judgment and their interpretation of the Hippocratic Oath. Depending on their individual training, the exigencies of the situation and the political climate in which they functioned, such judgment did not always lead to acceptable ethical conduct (viewed in light of contemporary standards). Still, ethically unacceptable experiments were infrequent, and it remained for the Nazi atrocities revealed at Nuremberg to provide the impetus for widespread discussion and the formulation of national standards and internationally acceptable guidelines concerning human experimentation.

The Nuremberg tribunal focused public attention, as well as that of the medical and scientific professions, on the horrors conducted in the name of scientific inquiry under the Nazi regime. With the knowledge of Hitler and at the instigation of Heinrich Himmler, Reichsführer of the S.S., and other members of the high command, those experiments were carried out, under the direction or organization of the various physicians in positions of authority in the Nazi regime,²¹⁵ upon unknown numbers of prisoners in the concentration camps. Though not an exhaustive list, some of the experiments and projects included the following: (1) immersion in tanks of cold water of varying temperatures for periods up to fourteen hours to develop techniques for rapid and complete resuscitation of German pilots downed at sea; (2) simulation of high altitude atmospheric conditions in decompression chambers, with autopsies then performed to study the effect of sudden pressure changes on the body; (3) attempted mass sterilization through castration doses of x-rays, treated diet and intrauterine injections apparently of silver nitrate, (4) mutilation of prisoners as experimental surgical subjects for the training of German surgical students; (5) injection of virulent typhus into prisoners to ensure a ready supply of virus for typhus experiments; (6) infliction of bullet wounds and incisions and introduction of bacteria into the wounds to study and treat infections; (7) shooting of prisoners with poisonous aconite bullets to study the effects of aconite poisoning; (8) forced ingestion of seawater into prisoners to test desalinization processes; (9) experimental bone transplantation; (10) ex-

²¹⁵ Dr. Karl Brandt held the highest medical position in Germany, that of Reich Commissioner for Health and Sanitation, and had supervisory authority over all military and civilian medical services. General Siegfried Handloser was the chief of medical services of the Wehrmacht. General Oskar Schroeder was chief of the medical services of the Luftwaffe. Dr. Karl Gebhardt was president of the German Red Cross. Dr. Paul Rostock was dean of the medical faculty of the University of Berlin, and Gerhard Rose was an internationally known specialist in tropical medicine. The other doctors were mainly staff doctors or consultants alleged to have direct contact with medical experiments. J. APPLEMAN, *supra* note 47, at 141-42.

ecution and dismemberment of prisoners to furnish "subhuman" skeletal specimens for an anthropological museum; and (11) injection of malaria to test malaria immunity.²¹⁶ While experiments involving desalinization,²¹⁷ malaria,²¹⁸ and high-altitude conditions²¹⁹ were conducted in the United States, such experiments were either performed solely on animals or were tested on animals before controlled experiments with appropriate safeguards were instituted on human subjects. Furthermore, in the United States the subjects were volunteers who, unlike their concentration camp counterparts, could refuse to participate in the experiment.

The twenty-three defendants in the Medical Case of the Nuremberg tribunal were tried by an international Military Tribunal under Control Council Order No. 10,²²⁰ and, of the sixteen defendants found guilty, fifteen were convicted of committing war crimes and crimes against humanity.²²¹ As part of its decision in the Medical Case, the Tribunal promulgated the Articles of the Nuremberg Tribunal as guide-

²¹⁶ *Id.* at 142-43; Enloe, *supra* note 46, at 801-03; Mellanby, *supra* note 46, at 148-49.

²¹⁷ Enloe, *supra* note 46, at 803.

²¹⁸ *Id.* at 803-04.

²¹⁹ *Id.* at 802.

²²⁰ The Tribunal was established by the London Agreement of August 8, 1945, pursuant to all previous declarations regarding war criminals and was signed by the United States, the Soviet Union, the United Kingdom and France "acting in the interest of all the United Nations." Article 6 of the Charter annexed to the London Agreement defined the crimes which came within the jurisdiction of the Tribunal, as did Order No. 10 promulgated later by the Control Council for Germany. Bierzanek, *The Prosecution of War Crimes*, in INTERNATIONAL CRIMINAL LAW, *supra* note 5, at 575-76. Establishment of such tribunals is an accepted practice under existing international law. J. APPLEMAN, *supra* note 47, at 12-13.

²²¹ War crimes encompass violations of the laws and customs of war. Crimes against humanity include murder, extermination, enslavement, deportation, and other inhumane acts committed against any civilian population, before or during a war, or persecutions on political, racial or religious grounds in execution of or in connection with any crime within the jurisdiction of the Tribunal, whether or not in violation of the domestic law of the country where perpetrated. These categories were so defined in the Charter annexed to the London Agreement, in Control Council Order No. 10 (art. 2) and in the Charter of the Tokyo Tribunal (art. 5). Bierzanek, *supra* note 220, at 576. Of the fifteen defendants guilty of at least these two crimes, seven were put to death, five were sentenced to life imprisonment, two were sentenced to twenty years imprisonment, and one was sentenced to fifteen years imprisonment. J. APPLEMAN, *supra* note 47, at 139-40. Petitions to the United States Supreme Court for review of these sentences were denied for lack of jurisdiction, a further recognition of the international character of the judgments. *Brandt v. United States*, 333 U.S. 836 (1948). *See, e.g., In re Yamashita*, 327 U.S. 1 (1946), in which criminal liability involving the death penalty was imposed for failure to supervise subordinates. The Supreme Court held that defendant was properly convicted because of "an affirmative duty to take such means as were within his power and appropriate in the circumstances to protect prisoners of war and civilian populations." But as argued by the dissent, this case lacked a clear resolution of the basis for liability for an omission. The trial proceedings failed to make clear whether defendant was convicted on the basis of his knowledge that atrocities had been committed by his subordinates or based on his negligence in not having such knowledge. *See Hughes, Criminal Omissions*, 67 YALE L.J. 590, 635-36 (1958).

lines for the legality of human experimentation.²²² Thus, the Nuremberg tribunal was an event of primary importance to human experimentation for three reasons: (1) it was the first example of cooperation; (2) it set forth the first internationally acceptable guidelines for such experimentation; (3) it focused the attention of the world community on the possible consequences of unethical and uncontrolled human experimentation, thereby providing the impetus to nations and national and international professional associations to formulate acceptable criteria.

Of the thirteen Nuremberg trials, historians have subsequently found room for disagreement with the verdicts of the Nuremberg tribunal in all the decisions except those involving the medical crimes. To date, significant world opinion has not come to the defense of the nature or manner in which the experiments were conducted in the Nazi concentration camps. Scientific achievement and the power of the scientific community to make drastic biological changes in human beings had by World War II, reached a point at which this power needed regulation by the world community.

The Articles of the Nuremberg Tribunal were generally accepted throughout the world as furnishing reasonable guidance for human experimentation, although problems arose concerning the application of certain principles.²²³ The main target for criticism was Article 1, which requires that an experiment be performed only after obtaining the voluntary consent of a subject who has the legal capacity to consent after that subject has been informed of the possible risks of the experiment. The objection has been raised that such a requirement would effectively curtail the use of the placebo²²⁴ and the study of mental illness and children's diseases.²²⁵ Questions have also been raised as to the desirability of informing the subject of all available information, the inability to inform him completely of the risks of the experiment because of the uncertain nature of the experiment, and the legal capacity of normal healthy volunteers (such as prisoners, students or assistants) to give consent in certain experiments and under certain conditions.²²⁶ Article 2, which states that the experiment should "yield fruitful results for the good of society" and that the experiment should not be "random and

²²² See note 56 & accompanying text *supra*.

²²³ See notes 66-87 & accompanying text *supra*.

²²⁴ Beecher, *supra* note 53, at 472-73.

²²⁵ *Id.* at 472; Bowker, *Legal Liability to Volunteers Testing New Drugs*, 88 CAN. MED. ASS'N J. 745, 748-49 (1963).

²²⁶ Beecher, *supra* note 53, at 472-73; Beeson, Bondy, Donnelly & Smith, *supra* note 56, at 458-62; Bowker, *supra* note 225, at 748; Welt, *Reflections on the Problems of Human Experimentation*, in CLINICAL INVESTIGATION IN MEDICINE: LEGAL, ETHICAL AND MORAL ASPECTS 126, 129 (I. Ladimer & R. Neuman eds. 1963).

unnecessary in nature” also has been attacked because of its undesirable connotations. Article 3, which concerns the justification for performance of the experiment, has been questioned on the basis of the investigator’s inability to guarantee success.²²⁷ Article 5, regarding experiments involving possible death or disabling injury and the investigator serving as a subject, has been criticized as being too strongly worded and too strict a requirement.²²⁸ Moreover, the concept of weighing the degree of risk against the humanitarian importance of the problem (Article 6) has been criticized as presumptuously evaluating the ultimate significance of one’s own research.²²⁹

Imperfect as the language or fundamental principles may seem, the Nuremberg code established the first internationally accepted safeguards and guidelines for the conduct of human experimentation. The Code remains a viable force. It squarely acknowledges the scientist’s responsibility for the respect of human rights.

With World War II and the Nuremberg tribunal providing the foundation for discussion and evaluation, the world community soon took steps toward the further establishment of safeguards for human rights in general and human experimentation in particular. At the Annual Assembly in Geneva in 1948, the World Medical Association, a newly formed organization that was the first body ever “to bring a substantial number of the doctors of the world together to think and act concertedly,”²³⁰ formulated its Declaration of Geneva, a restatement of the basic principles of medical conduct intended to update the Hippocratic Oath. Among the pledges it set forth for a physician are these:

I solemnly pledge myself to consecrate my life to the service of humanity. . . . The health of my patient will be my first consideration; . . . I will maintain the utmost respect for human life from the time of conception; even under threat, I will not use any medical knowledge contrary to the law of humanity.²³¹

This pledge has gained increasing acceptance and has been incorporated into the written codes of ethics of many national medical associations.²³²

In 1952 Pope Pius XII delivered a speech in which he expressed the

²²⁷ Beecher, *supra* note 53, at 474; Clegg, *Human Experimentation*, 7 *WORLD MED. J.* 77, 78 (1960); Welt, *supra* note 226, at 129-30.

²²⁸ Beeson, *supra* note 57, at 474; Welt, *supra* note 226, at 130. This principle was found to have been regarded too casually by Drs. Mandel and Southam at the Brooklyn Jewish Chronic Disease Hospital, *Hyman v. Jewish Chronic Disease Hospital*, 21 App. Div. 2d 495, 251 N.Y.S.2d 818 (1964).

²²⁹ Welt, *supra* note 226, at 130.

²³⁰ *The Declaration of Geneva, 1948: A 1971 Reappraisal*, 2 *MED. J. AUSTL.* 735 (1971).

²³¹ *Id.*

²³² *Id.*

position of the Roman Catholic Church relative to human experimentation and the moral limits involved.²³³ Stating that there is a "moral limit to the doctor's action taken with the consent of the patient" and that the moral law "sets up limits to the 'medical interest of the patient,'" the Pope explained that there are serious limitations on the consent of the patient, as viewed by the Church.²³⁴ This position has remained basically unchanged, and, though clothed in religious terms, it remains as a universal law governing the respect of human rights over and above scientific achievement.

In 1954, the World Medical Association, at its Eighth General Assembly in Rome, adopted the Principles for Those in Research and Experimentation.²³⁵ These five basic principles stress that (1) experimentation should be conducted only in a scientific manner by qualified individuals who adhere to general rules of respect for the individual's rights; (2) operations or treatment of a daring nature may be performed on sick patients only in desperate cases; (3) the researcher bears primary responsibility in human experimentation; (4) informed consent must be obtained in writing for experimentation on both sick and healthy patients and (5) publication of the first results of experimentation should be done with prudence and discretion to avoid the detrimental effects of premature and unjustified statements.²³⁶

In the following year, the Public Health Council of the Netherlands submitted its Report on Human Experimentation to that nation's Minister of Social Affairs and Health.²³⁷ In addition to defining and discussing various aspects of human experimentation, such as the approval of the subject, risk involved, responsibility, justifiability and dangerous experiments, the Council recommended numerous guarantees and standards, the more noteworthy of which are the following:

- 1) A recommendation for the study of publications to avoid unnecessary repetition of experiments;

²³³ Address by Pope Pius XII: Moral Limits of Medical Research and Treatment, First International Congress on Histopathology of the Nervous System (Sept. 14, 1952), in Beecher, *supra* note 53, at 470, 473, 475.

²³⁴ The first such limitation is that although the individual does not possess the right to destroy or mutilate his body, he may allow parts of it to be destroyed or mutilated in order to preserve the good of his being as a whole. Secondly, an individual may participate as a subject in scientific investigations, only so long as such investigations do not violate superior values, such as the doctor-patient relationship and the patient's right to the physical and moral integrity of his body and soul. *Id.* See Giuseppe, *Human Experimentation—A World Problem from the Standpoint of Spiritual Leaders*, 7 *WORLD MED. J.* 80 (1960).

²³⁵ World Medical Association, *Principles for Those in Research and Experimentation*, 2 *WORLD MED. J.* 14 (1955).

²³⁶ *Id.* at 14-15.

²³⁷ Public Health Council of the Netherlands, *Report on Human Experimentation*, in *CLINICAL INVESTIGATION IN MEDICINE*, *supra* note 226, at 154-58.

- 2) The investigator should consult other experts on the research project in order to intensify the sense of responsibility;
- 3) If considerable risk is involved, the experiment is not in accord with the object and purpose of medicine;
- 4) A practicing physician should not become an investigator on his own patient, if the experiment involves danger. A body of advisors should be consulted;
- 5) Experiments on institutionalized old people and children and on the insane, or on prisoners, which involves dangerous risks, inconvenience or pain are not approved. All experiments on the dying under any circumstances are disapproved;
- 6) The "utmost restraint" must be exercised in experiments on patients deemed to have an incurable malady, even though they volunteer as subjects;
- 7) Publication of articles describing human experiments that are contrary to medical ethics is strongly criticized; and it is recommended that medical journals refuse to publish articles based on unethical experiments; and
- 8) To interpret and apply these principles and standards, the Committee recommends establishment of a permanent advisory committee of men experienced in human experimentation.²³⁸

The World Medical Association later presented a summary of this report specially prepared for it.²³⁹

In September, 1961, the Ethical Committee of the World Medical Association formulated its provisional conclusions from its study of experiments involving humans and presented them in a Draft Code of Ethics on Human Experimentation to the General Assembly of the World Medical Association.²⁴⁰ This draft version was later modified and prefaced by a general statement on medical ethics and the necessity of research in medicine. The final version was accepted at the meeting of the World Medical Association at Helsinki in 1964 and is known as the Code of Ethics on Human Experimentation of the World Medical Association.²⁴¹

A brief comparison between the draft version and the final version is useful, since it can be assumed that any modifications, deletions or additions were done purposely, possibly as a result of international dialogues in the interim. Provisions in the final version not stated in the draft version are:

- 1) Clinical research cannot legitimately be carried out unless the importance of the objective is in proportion to the inherent risk to the subject.
- 2) In the purely scientific application of clinical research carried out on a

²³⁸ *Id.*

²³⁹ Public Health Council of Netherlands, *Human Experimentation*, 4 *WORLD MED. J.* 299 (1957).

²⁴⁰ World Medical Association, *Draft Code of Ethics on Human Experimentation*, 2 *BRIT. MED. J.* 1119 (1962).

²⁴¹ See notes 57-65 & accompanying text *supra*.

human being it is the duty of the doctor to remain the protector of the life and health of that person on whom clinical research is being carried out; and

3) Consent should as a rule be obtained in writing. However, the responsibility for clinical research always remains with the research worker; it never falls on the subject, even after consent is obtained.

The draft version explicitly stated that a doctor could extend an experiment beyond the possible benefit of his patient or combine clinical research with the personal care of the patient solely for the acquisition of knowledge, only if the full consent of the patient has been previously obtained. However, the final version provided that a doctor could combine research with professional care to acquire new medical knowledge only to the extent that clinical research is justified by its therapeutic value for the patient.²⁴² Even though the final version stated that non-therapeutic clinical research could not be undertaken without the subject's free and fully informed consent, it allowed the consent of the legal guardian to be procured in the case of a legal incompetent (without specifically mentioning children or mental patients). The draft version also would not allow those children in institutions who were not under the care of relatives or those persons residing in mental hospitals or in hospitals for mental defectives to be subjects of human experimentation.

Provisions of the draft version totally deleted from the final version and without parallel reference are the following:

- 1) Prisoners of war, military or civilian, should never be used as subjects of experiment;²⁴³
- 2) Civilians detained in any place as a result of military invasion or occupation, or for administrative or political reasons, should never be used for human experiment;²⁴⁴ and
- 3) Persons detained in prisons, penitentiaries, or reformatories—being "captive groups"—should not be used as subjects of experiment; nor persons incapable of giving consent because of age, mental incapacity, or of being in a position in which they are incapable of exercising the power of free choice.

In the period between the draft and final version of the World Medical Association's code, the British Medical Research Council issued its Statement on Responsibility in Investigation on Human Subjects to "serve as a guide to medical men engaged in this kind of work."²⁴⁵ While many portions of the statement are similar to the codes previously discussed, certain positions are worth noting. The Council separated investigations on human subjects into two categories—those which contribute to the benefit of the individual and those which contribute to

²⁴² See p. 1610 *supra*.

²⁴³ See notes 301-04 & accompanying text *infra*.

²⁴⁴ *Id.*

²⁴⁵ Medical Research Council, *Responsibility in Investigations on Human Subjects*, 2 BRIT. MED. J. 178, 178 (1964).

medical knowledge but are of no direct benefit to the individual. In those investigations that are beneficial to the individual and in which a novel procedure is contemplated, the Council believed that the doctor "may assume the patient's consent to the same extent as he would were the procedure entirely established practice" and that the "question of novelty is only relevant to the extent that in reaching a decision to use a novel procedure the doctor, being unable to fortify his judgment by previous experience, must exercise special care."²⁴⁶ In a double blind study where a control might receive no treatment, the control must be fully advised of this fact and give his fully informed consent. In investigations of no direct benefit to the individual, fully informed consent must also be given. In these cases the Council recognized the British view that such investigations could not be conducted on children under twelve years of age even with their parents' or guardians' consent. In the case of the mentally disordered, procedures which carry a risk of harm to the subject could not be undertaken without fully informed consent.

The Council further stated that:

The head of a department where investigations on human subjects take place has an inescapable responsibility for ensuring that practice by those under his direction is irreproachable.

In the same way the Council feels that, as a matter of policy, bodies like themselves that support medical research should do everything in their power to ensure that the practice of all workers whom they support shall be unexceptionable and known to be so.²⁴⁷

The Council also believed that specialized scientific societies from all branches of medicine must create and maintain a body of precedents which would guide individual investigators. Finally, it asserted that "any account of investigations on human subjects should make clear that the appropriate requirements have been fulfilled, and, further, that no paper should be accepted for publication if there are any doubts that such is the case."²⁴⁸

Both the Helsinki code and the British statement were well-received by the medical profession throughout the world, although with some reservations. While some physicians thought that the deletion in the Helsinki code of those clauses in the draft versions previously discussed weakened the code and made it less concise,²⁴⁹ others thought that there were acceptable reasons for the deletion and that other clauses compensated for the deletion.²⁵⁰ There was some discussion that the British

²⁴⁶ *Id.*

²⁴⁷ *Id.* at 179.

²⁴⁸ *Id.* at 180.

²⁴⁹ *Ethics of Human Experimentation*, 2 BRIT. MED. J. 135, 136 (1964).

²⁵⁰ *Ethics of Clinical Research*, 2 MED. J. AUSTL. 309 (1964).

statement offered "a more realistic and sounder guide to the research worker who is enlarging the field of human knowledge by investigating human beings,"²⁵¹ and the consensus of opinion seemed to be that it at least gave fuller and more detailed guidance than the Helsinki code.²⁵²

B. COMPARATIVE ASPECTS OF HUMAN EXPERIMENTATION

At this juncture it is proper to examine the effect of this initial international activity on the regulation of human experimentation in various nations. A significant early effort to communicate the regulatory practices of various nations was presented in a 1960 international symposium on human experimentation.

In France at this time there was no regulation of surgical intervention and scientific research for a nontherapeutic purpose. However, experimentation was legally permissible only if designed to assist in the care of the patient without exposing him to a serious and certain danger. No experimentation was allowed solely for a scientific purpose, devoid of the idea of treating a sick or healthy person. Even the consent of the party concerned was not sufficient to give permission in such a case.²⁵³

In India, a code of ethics governing human experimentation had not yet been established. There was no law prohibiting experimentation on human beings as long as such experiments were not harmful to health or life. The Indian Council of Medical Research and the Indian Medical Association had only issued general considerations and broad principles governing the conduct of such experiments. However, the Therapeutic Trials Committee of the Indian Council on Medical Research had issued definite instructions concerning therapeutic trials of drugs conducted under its auspices. "As a rule, at present, inmates of prisons, mental institutions, etc., are not used as subjects for human experiments nor are patients used for investigations which have no relation to the condition for which they have been admitted to the hospital."²⁵⁴

Although a considerable amount of human experimentation has been done in Japan, neither the Japanese government nor the Japanese Medical Association had promulgated a code of ethics governing experiments on human beings, nor was there an institution providing general guidance for such experiments. However, the Japanese Medical Association endorsed the 1954 resolution of the World Medical Association²⁵⁵ and recommended that voluntary, informed, written consent, prior animal experimentation and investigator qualifications be emphasized

²⁵¹ *Ethics of Human Experimentation*, *supra* note 249, at 135, 136.

²⁵² *Id.* at 136; *Ethics of Clinical Research*, *supra* note 250, at 309.

²⁵³ Gosset, *Special Report: France*, 7 *WORLD MED. J.* 84 (1960).

²⁵⁴ Mitra, *Special Report: India*, 7 *WORLD MED. J.* 84-85 (1960).

²⁵⁵ See notes 235-36 & accompanying text *supra*.

in any subsequent international code of ethics on human experimentation.²⁵⁶

During this period in the Philippines there was apparently very little human experimentation conducted, primarily due to the lack of scientific incentive and the beliefs of the people. Of the experimentation done on human subjects approximately 90 percent involved the clinical trial of imported drugs tested on animals and humans in the country of their origin and 10 percent involved the use of penitentiary inmates. However, as human experimentation increased in the Philippines, the necessity for regulation was recognized.²⁵⁷

In Thailand a law existed which regulated medical practice and also included a code governing the ethics of practitioners, but there was no specific law or code governing experiments on human beings. The Medical Association of Thailand had not issued any guidelines on human experimentation. Physicians were free to use any method of treatment or any medicine on their patients, so long as it was ethically thought to benefit the patients and did not defame the medical profession. Controlled therapeutic trials of drugs were practiced only in large medical centers under the responsibility of the physician concerned, and the use of inmates of both penal and mental institutions for controlled prophylactic or therapeutic trials was prohibited. Undertaking experiments on patients without relation to the condition for which they were admitted to the hospital were voluntary matters and rarely practiced.²⁵⁸

More recently, among some of the member States of the Council of Europe, a number of principles have emerged in the context of experimentation. For example, in the case of research experiments, the physician is responsible to inform his patients as fully as possible. Additionally, in cases where there is criticism of treatment without informed consent, only written consent should be accepted in the field of experimentation. With respect to compensation of subjects injured during experimentation, where the law of contract is applicable on the grounds of a physician's civil liability in using experimental procedures, waivers of claims for compensation are not considered valid, unless they are expressly incorporated into the contract between doctor and patient. Even then, the waiver is strictly construed in the interest of the patient.²⁵⁹ Finally, a code of responsibility governing the conduct of physi-

²⁵⁶ Ono, *Special Report: Japan*, 7 WORLD MED. J. 85 (1960).

²⁵⁷ Atienza, *Special Report, Philippines*, 7 WORLD MED. J. 85 (1960). In 1966, the Philippine Medical Profession adopted a code of medical ethics which contained a provision that a physician should adhere to the generally accepted principles promulgated by the World Medical Association. Philippine Medical Association, *Code of Medical Ethics of the Medical Profession in the Philippines*, 42 J. PHILIPPINES MED. ASS'N 271 (1966).

²⁵⁸ Pholpoke, *Special Report: Thailand*, 7 WORLD MED. J. 86 (1960).

²⁵⁹ Giesen, *supra* note 3, at 212-13.

cian-investigators has recently been enacted in Italy.²⁶⁰

In Scandinavian countries no official statistics on the extent of experimentation involving human subjects are available. However, experiments in which violations of human rights were reported have not occurred, largely because of these countries' reactions to the Nazi medical experimentation in World War II. It is noteworthy that under Danish law there are as yet no general legal rules expressly dealing with experimentation on human subjects. Moreover, while there is a general objection to the use of prisoners in experiments, Danish law does not expressly forbid it.²⁶¹

French legislation²⁶² also has recently addressed the subject of human experimentation for pure research. The object of that legislation is the regulation of medical and biological laboratories. Among the regulations are the requirements of prior authorization for use of experimental products,²⁶³ and the Minister of Health has the right to establish a list of persons authorized to engage in such research.²⁶⁴ Authorized laboratories and personnel and the directors of research also can be held personally responsible and are subject to inspection by the Ministry of Health.²⁶⁵ These regulations are linked to penal responsibility for injury caused in the conduct of such experimentation, although it is not expressly prohibited.²⁶⁶ The Penal Code further prohibits experimentation on persons detained in public institutions.²⁶⁷ Furthermore, France enacted a Code of Medical Ethics in 1979²⁶⁸ which provides in Article 19 that biological studies must be preceded by adequate testing before being applied to human subjects and then only for therapeutic purposes and at the express request of the patient, provided he knows of its consequences and effects.

In Canada, recent legislation in the Quebec Civil Code has attempted to set standards under which consent may be regarded as properly given. One commentator has stated that while the Quebec statute has reduced the risk of abuse because of the safeguards surrounding experimentation on minors, the statute is not clear on the lower limit of

²⁶⁰ Codice di Deontologica Medica, Capo VI, art. 48-52, Federazione Nazionale Degli Ordini dei Medici (1978).

²⁶¹ Larsen, *supra* note 44, at 170, 175.

²⁶² Law No. 75-626 of July 11, 1975. This statute follows the directives of the European Economic Community (EEC) on pharmacological and toxicological laboratories and research, as presented in the EEC decision of May 20, 1975.

²⁶³ CODE OF PUBLIC HEALTH, art. 601, as amended by an ordinance of Sept. 23, 1976 (to be issued by the Permanent Biological Comm'n under Article 759 of that Code).

²⁶⁴ Decree No. 75-1024 of Nov. 5, 1975.

²⁶⁵ CODE OF PUBLIC HEALTH, art. 757.

²⁶⁶ PENAL CODE, art. 318.

²⁶⁷ *Id.* art. 380, para. 3; Decree No. 72-852 of Sept. 12, 1972.

²⁶⁸ Decree No. 79-506 of June 28, 1979.

consent. Thus, the statute may not cover experiments on children, and the question thus remains whether or not Quebec law completely forbids experiments on children.²⁶⁹

Finally, in both the United Kingdom and Israel there are long-standing practices against allowing prisoners to participate in experiments involving human subjects.²⁷⁰ In fact, outside of the United States, experimentation using prisoners as volunteer subjects is almost uniformly forbidden.²⁷¹

In this developing atmosphere of recognition that controls are desirable but that codification of regulations and safeguards is inadequate, regulation of drug experimentation and human experimentation in general continued to evolve under the FDA and NIH in the United States.²⁷² Also, the British Medical Research Council published its guidelines for investigation on human subjects.²⁷³

Two other noteworthy statements of professional organizations concerning human experimentation should be mentioned. The first is the Australian National Health and Medical Research Council's Statement on Human Experimentation of 1966.²⁷⁴ While this declaration added no new standards, the mere adoption of such a code in a country with a medical profession of such a high reputation is an achievement, especially when the code subsequently gained wide acceptance as the official policy on human experimentation of other grant-giving bodies, hospi-

²⁶⁹ Bowker, *supra* note 1, at 173-74. The author also discusses, at 170-71, the case of Halushka v. University of Saskatchewan, (1965), 53 D.L.R. (2d) 436 (Sask. C.A.), in which plaintiff volunteered to take part in the study of a new anaesthetic. While under the anaesthetic, he suffered a cardiac arrest. He was revived, but the harm to his health was considerable. Plaintiff had signed a consent form stating that he fully understood what was proposed to be done. Nevertheless, the jury found that he had not consented to the test that was done and, *inter alia*, that the doctors were negligent in failing to fully explain to him the risks involved with the test at the time of consent. The Court of Appeal held that in research the duty of explanation is at least as great as, if not greater than, that owed in the traditional doctor-patient relationship. One important problem unresolved by Halushka is that like the Quebec statute, it does not provide a lower limit in the common law for the age of consent. Bowker, *supra* note 1, at 174.

²⁷⁰ Daube, *supra* note 21, at 10.

²⁷¹ This finding was based on a survey of seven European nations (Belgium, France, Germany, Holland, Italy, Spain, and Sweden), five English speaking countries (Australia, Canada, New Zealand, South Africa, and the United Kingdom), four Latin American nations (Brazil, Colombia, Mexico, and Peru) and Japan. Jaffe & Snoddy, *An International Survey of Clinical Research in Volunteers*, in U.S. NAT'L COMM'N FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, HEW, RESEARCH INVOLVING PRISONERS, *supra* note 77, at 9-2, 9-4.

²⁷² See notes 119-214 & accompanying text *supra*.

²⁷³ Medical Research Council, *supra* note 245.

²⁷⁴ Nat'l Health and Medical Research Council, *Statement on Human Experimentation*, 2 MED. J. AUSTL. 325 (1966).

tals, and research institutions in Australia.²⁷⁵

In 1967, a committee established the previous year by the Royal College of Physicians of London to study supervision of clinical investigation and the best methods for implementation of such supervision submitted its report.²⁷⁶ Although this committee accepted the Helsinki Code and the Australian Medical Research Council statement as defining the ethical situation and considered that all clinical investigators should be familiar with these recommendations, it had reservations concerning the ability of the documents to provide more than general guidance or to apply to specific problems. Therefore, the committee recommended the establishment of a procedure for supervision of clinical investigation by a peer review group which would separately approve each human experimentation project within the institution.²⁷⁷ This idea is gaining widespread acceptance, as witnessed by the review of FDA, NIH and HHS guidelines and the Medical Research Council statement.

C. ASSESSMENT OF INTERNATIONAL AND NATIONAL EFFORTS

A system of enlightened, ethical and parochial review coupled with fully informed and free consent given by the patient-subject is the most effective means of conducting clinical investigation while safeguarding the rights of the patients. However, because of the belief that a responsible, ethical and informed investigator is the one on whom the ultimate responsibility for the conduct of the experiment and the welfare of the subject lies, not all of the codes and articles discussed²⁷⁸ recommend peer review systems and mandatory informed consent of the patient-subject. Yet, the lack of such a peer review system would not contain the dimension of checks and balances. If a responsible investigator is always capable of making the "right" decision regarding human experimentation, further control need not be required. But even if nearly all of the investigators made the ethically correct decision, there would still remain that small fraction of cases where the patient's rights would be violated. With a peer review system, more than one viewpoint on a particular experiment can be considered. While one investigator may not consider all aspects of the situation because of his proximity to the experiment, other medical or scientifically trained individuals and responsible laymen should be able to consider the spectrum of alternatives and

²⁷⁵ Morris, *Compassion, Caution and Courage*, 1 MED. J. AUSTL. 1111, 1112 (1968).

²⁷⁶ Royal College of Physicians, *Supervision of the Ethics of Clinical Investigations in Institutions*, 3 BRIT. MED. J. 429 (1967).

²⁷⁷ *Id.* at 429-30.

²⁷⁸ See, e.g., H. BEECHER, *supra* note 7, at 1360; Beecher, *Some Guiding Principles for Clinical Investigations*, 195 J.A.M.A. 157 (1966); *Experiments in Man*, 3 BRIT. MED. J. 385, 386 (1967).

recommend a proper course of conduct. If an experiment involving human subjects is ethical and contains the proper safeguards for the patient, it should withstand scrutiny.

Despite committee consideration of a variety of viewpoints, neither the committee members nor the investigators undergo the experimental procedures. Thus, if they decide that a particular experiment should be conducted on an individual, the fate of that individual is set by nonparticipants. For that reason, the ultimate decision to continue participation in an experiment should reside in the subject. If the subject is to choose properly, the investigator must fully inform him of all known information relevant to the experiment and any alternative procedures. Only then will the subject's voluntary consent be as fully informed as practicable. Since he may be willing to submit to experimentation not in accordance with ethical principles, the review committee must still be able to reject the experiment.

The alternative system of allowing the investigator to make the determination whether an experiment should be done on an individual is too susceptible to error, no matter how seldom it may occur, because the potential exists for the investigator's decision to be clouded by his subjectivity to the work and the result he hopes to achieve. He may too easily forget that the patient-subject deserves greater consideration than the experiment. Even though medical research is essential, it must not be done to the unnecessary detriment of the individual. It is too easy for the investigator to put himself above the subject, as evidenced by the words of Dr. Southam, who, when questioned as to his reason for injecting patients with live cancer cells but not injecting himself, replied.

I would not have hesitated if it would have served a useful purpose. But to me it seemed like false heroism, like the old question whether the General should march behind or in front of his troops. I do not regard myself as indispensable—if I were not doing this work someone else would be—and I did not regard the experiment as dangerous. But, let's face it, there are relatively few skilled cancer researchers, and it seemed stupid to take even the little risk.²⁷⁹

The investigator must remember that, even though he hopes that the

²⁷⁹ *Human Experimentation: The Rights of Patients*, 1 MED. J. AUSTRAL. 755 (1966). The error in judgment of which Dr. Southam was guilty in this matter was not the injection of the live cancer cells into the patients. He was guilty of not fully informing them of all the known circumstances surrounding the experiment and then obtaining their fully informed voluntary consent. For this reason, he was found guilty of "unprofessional conduct" and of "fraud and deceit in the practice of medicine" by a group of his peers and the Regents of the University of the State of New York and was suspended from practice for one year (although the execution of this suspension was stayed and he was placed on probation and still allowed to practice.) See, e.g., *Hyman v. Jewish Chronic Disease Hospital*, 21 App. Div. 2d 495, 251 N.Y.S.2d 818 (1964); *Halushka v. University of Saskatchewan*, (1965), 53 D.L.R. (2d) 436 (Sask. C.A.), *supra* note 269.

experiment will ultimately be for the benefit of mankind, he could not accomplish this purpose without his subjects. He has no reason, therefore, to place himself above them and to assume risks for them that he would be reluctant to face himself. This relationship has been accurately summarized: "When research involves human subjects, the research investigator must always remember that in the final analysis there is no substitute for his volunteer. A person of such importance should be given the consideration and respect which his unique position merits."²⁸⁰

After this review of the present internationally accepted or promulgated guidelines for human experimentation, two major questions remain: (1) Is it reasonable to expect patients or healthy individuals to volunteer as experimental subjects if fully informed? (2) Is it reasonable to expect nations to cooperate to control or regulate human experimentation? For the answer to the first question, a report of three studies analyzing the problem of the volunteer in medical research has revealed the varying willingness of different strata of society in the United States to participate as volunteers in medical research.²⁸¹ The main conclusion of this report is that patients or healthy individuals will volunteer as experimental subjects if fully informed. The answer to the second question is also affirmative as evidenced by the cooperation in the development of the polio vaccine²⁸² and the study of rheumatic heart disease.²⁸³ Based on these and other examples, as well as the aforementioned inter-

²⁸⁰ *Protection of Human Rights in Medical Research*, 101 CAN. MED. ASS'N J. 237, 238 (1969).

²⁸¹ Martin, Arnold, Zimmerman & Richart, *Human Subjects in Clinical Research—A Report of Three Studies*, 279 NEW ENGLAND J. MED. 1426 (1968).

²⁸² The conquest of poliomyelitis began at the Rockefeller Institute with the discovery of the polio virus in 1909, followed by the development of the Salk vaccine. This was an attenuated live virus tested under the auspices of the National Foundation for Infantile Paralysis in 1954. Later confirmatory field trials were conducted in the Soviet Union and Czechoslovakia (1960) and in polio epidemics in the United States in the early 1960s. In 1955, Sabin developed an oral polio vaccine in England, which also received comparative trials in several cities of the United States, Czechoslovakia, Poland, Mexico, and the Belgian Congo. It was also tested in West Berlin and in other cities of South and Central America. Finally, international conferences in New Jersey, Moscow, Washington, D.C., and Copenhagen under the auspices of the World Health Organization and other organizations gathered and evaluated information for the manufacture, distribution and efficacy of the various polio vaccines. Paul, *Status of Vaccination Against Poliomyelitis with Particular Reference to Oral Vaccines*, 264 NEW ENGLAND J. MED. 651, 651-57 (1961).

²⁸³ The ongoing cooperative study of rheumatic heart disease is notable among many other similar efforts to control disease. This study was conducted under the joint sponsorship of the Medical Research Council of Great Britain and the Council on Rheumatic Fever and Congenital Heart Diseases of the American Heart Association. Densen & Rutstein, *Natural History of Rheumatic Fever and Rheumatic Heart Disease: Ten-Year Report of a Cooperative Trial of ACTH, Cortisone and Aspirin*, 2 BRIT. MED. J. 607 (1965) reprinted in 93 CAN. MED. ASS'N J. 519 (1965) and 32 CIRCULATION 457 (1965). See also *International Trials and Pediatric Nephrology*, 300 NEW ENGLAND J. MED. 254 (1979) (discussing the success of the International Study of Kidney Disease in Children).

nationally accepted guidelines and codes, it is clear that nations are prepared to cooperate in the regulation of human experimentation.

VII. SYNTHESIS AND PROGNOSIS: THE NEED FOR AN
INTERNATIONAL DOCUMENT ON HUMAN
EXPERIMENTATION

Unlawful human experimentation is a single phenomenon which from the standpoint of the law occurs in two contexts. The first, concerns human experimentation during armed conflict, and the second is analogous to torture during peacetime. However, torture in time of peace does not adequately encompass all human experimentation, leaving a need to define the criminal aspects of human experimentation and thereby complete the symmetry between the law of war and the law of peace. Moreover, lawful human experimentation implies certain principles, among which is placing the health and welfare of human subjects foremost. Thus, nations also can declare their adherence to certain moral principles, following the model of the Universal Declaration of Human Rights,²⁸⁴ rather than adopt a system of legally binding prescriptions, on the model of human rights conventions. Besides these areas of human experimentation, there is also a "grey area" which falls within the potential regulatory schemes of nations. This area is fundamentally a problem of administrative law since penalties would be imposed for violation of administrative rules, for example with respect to the elements of consent or the conditions of the experiment.

Thus, there is an interrelationship between several areas of the law on the regulation of human experimentation. The first source is international law as it regulates the conduct of states and imposes certain duties upon them. The second is the national laws of signatory nations which should embody the proscriptions of an international convention on this subject. Finally, there are administrative structures of implementation which would enforce national law.

The three contexts of human experimentation (the law of war, the law of peace, and the principled approach) require the elaboration of separate documents for the purpose of defining the concepts and principles in each area. It is proposed that the first document be a draft convention in the nature of international law conventions. It should contain (1) the provisions of the Geneva Conventions prohibiting any type of human experimentation in time of war; (2) an absolute prohibition on human experimentation which would fall within the general nature of crimes against humanity; (3) a prohibition on crimes against humanity for the purpose of achieving a political objective and used as

²⁸⁴ G.A. Res. 217A(III), 3 U.N. GAOR 71, U.N. Doc. 8/810 (1948).

an adjunct for torture;²⁸⁵ and (4) a prohibition on human experimentation in prisons, mental institutions and other conditions of detention where it is conclusively presumed that the individual is incapable of giving consent.²⁸⁶

The second document on crimes against humanity should define the principles on which human experimentation is lawfully conducted. Two broad categories would be encompassed by such a document: (1) experimentation in principle declared to be in violation of human rights and (2) experiments of therapeutic value but conditioned by guidelines regarding the subjects and contexts to be applied. The focus of this proposed document should be on defining the elements of informed consent and ensuring that experimenters obtain it.

Finally, the administrative level document will present guidelines for national legislation and control mechanisms at the national legislative level, for example institutional peer review committees.

The basis for a specialized convention on human experimentation

²⁸⁵ It has been proposed that unlawful human experimentation be declared a crime punishable under international law. M. BASSIOUNI, INTERNATIONAL CRIMINAL LAW 85-86 (1980). Article IX of the Draft Code provides:

Section 1. *Acts of Unlawful Medical Experimentation*

1.0 The crime of unlawful medical experimentation consists of any physical and/or psychological alterations by means of surgical operations or injections, ingestion or inhalation of substances inflicted by or at the instigation of a public official, or for which a public official is responsible and to which the person subject to such experiment does not grant consent as described in Section 2.

Section 2. *Defense of Consent*

2.1 For the purpose of this Article a person shall not be deemed to have consented to medical experimentation unless he or she has the capacity to consent and does so freely after being fully informed of the nature of the experiment and its possible consequences.

2.2 A person may withdraw his or her consent at any time and shall be deemed to have done so if he or she is not kept fully informed within a reasonable time of the progress of the experiment and any development concerning its possible consequences.

Id. at 85.

²⁸⁶ United States law has sought to achieve patient rights which embody the concept that a patient be capable of giving his informed consent. That view is a necessary precondition to any argument favoring a confined individual's right to accept or refuse treatment. *See* R. SCHWITZGEBEL, LEGAL ASPECTS OF THE ENFORCED TREATMENT OF OFFENDERS (HEW Pub. No. (ADM) 79-831, 1979). *See also* notes 98-113 & accompanying text *supra*. However, since legal systems throughout the world fail to afford a similar degree of protection to human subjects, the opportunities for abuse are rampant. Consequently, it is proposed that any scheme for international regulation include a prohibition against experimentation on categories of persons shown in practice to be readily misled or coerced into participating in unlawful experiments. By presuming them incapable of giving informed consent, they would enjoy greater protection by virtue of their status as inmates of detentive or domiciliary institutions.

See generally U.S. NAT'L COMM'N FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, HEW RESEARCH INVOLVING CHILDREN, *supra* note 75, at 21-26; U.S. NAT'L COMM'N FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, HEW, RESEARCH INVOLVING PRISONERS, *supra* note 77; H. BEECHER, *supra* note 7, at 52-78; C. FRIED, *supra* note 15, at 61-63; Daube, *supra* note 21, at 10.

is provided primarily by the international documents on human rights. The proliferation of those documents since World War II is evidence of the desire among nations to promote human rights in a widening variety of contexts. A convention for the protection of human subjects would be consonant with the attitude of the world community by guaranteeing additional rights heretofore implicit in many such documents but not yet singled out.²⁸⁷ This current lack of specificity gives rise to certain problems especially with respect to the nature and extent of the duty of States to protect experimental subjects and the scope of the situations in which human rights guarantees may be invoked. A survey of the existing documents reveals the doctrinal basis which justifies a specialized convention and the lack of specificity which necessitates it.

The starting point for analysis of international instruments dealing with human rights is the Universal Declaration of Human Rights of 1948.²⁸⁸ Many of its provisions are now recognized as declaratory of customary international law, and therefore as binding on all States. Several States have also accepted the Declaration as binding.²⁸⁹ This document has been invoked as law on many occasions and by juridical consensus has become the authentic interpretation of the human rights provisions of the United Nations Charter.²⁹⁰ Still, the Declaration is perceived as the seminal force which creates new human rights instruments rather than specifying such rights. Thus, the Universal Declaration lacks the specificity necessary to provide the linkage to human experimentation. Moreover, it is vulnerable to the argument that because it is not a treaty, it may not afford adequate protection to experi-

²⁸⁷ Given the fact that the impetus for the human rights movement was in large measure due to the physical and spiritual devastation of World War II and that the war crimes convictions for unlawful human experimentation have never been challenged as deficient under international law, it is ironic that a convention for the regulation of human experimentation does not yet exist. See generally L. HENKIN, *HOW NATIONS BEHAVE* 229-37 (1979).

²⁸⁸ See note 284 *supra*.

²⁸⁹ Higgins, *Conceptual Thinking About the Individual in International Law*, 24 N.Y.L. SCH. L. REV. 11, 22 (1978); Humphrey, *The Implementation of International Human Rights Law*, 24 N.Y.L. SCH. L. REV. 31, 32-33 (1978); van Dijk, *International Law and the Promotion and Protection of Human Rights*, 24 WAYNE L. REV. 1529, 1543 (1978). See generally Lillich, *The Role of Domestic Courts in Promoting International Human Rights Norms*, 24 N.Y.L. SCH. L. REV. 153 (1978).

²⁹⁰ Humphrey, *supra* note 289, at 33. The Charter of the United Nations refers to problems of human rights in its Preamble and in six separate Articles. However, it does not specifically enumerate any of these rights. This task has been left to the Universal Declaration of Human Rights and other conventions. See UNITED NATIONS ACTION IN THE FIELD OF HUMAN RIGHTS 6 (1980) [hereinafter referred to as ACTION]. It is generally agreed, however, that the Charter imposes obligations on States to respect human rights. The possibility of coercive sanctions are precluded by Article II except where the violations are so serious as to pose a threat to international peace or security. Moreover, the advisory opinions which may be requested on legal matters under Article 96 are open to political influence which detract from justice and consistency. Humphrey, *supra* note 289, at 34-37.

mental human subjects.²⁹¹

The Covenant on Civil and Political Rights, which springs from the Universal Declaration by expressly dealing with matters implicit therein,²⁹² prohibits human experimentation without the free consent of the subject.²⁹³ However, the Covenant is hobbled by weak implementation provisions.²⁹⁴

Likewise, the European Convention for the Protection of Human Rights and Fundamental Freedom is an outgrowth of the Universal Declaration and provides the same basic rights as the Convention on Civil and Political Rights. Although the enforcement mechanisms of the European Convention are relatively strong,²⁹⁵ any State party to the

²⁹¹ See STATUTE OF THE INTERNATIONAL COURT OF JUSTICE, Art. 38(1). See also van Dijk, *supra* note 289, at 1541-43.

²⁹² G.A. Res. 2200 A, 21 U.N. GOAR Supp. (No. 16) 49, U.N. Doc. A/6316 (Dec. 16, 1966) [hereinafter referred to as G.A. Res. 2200A].

²⁹³ Among the prohibitions specifically mentioned in the Covenant are ones against arbitrary deprivation of life, torture, cruel, inhuman or degrading treatment or punishment, slavery and forced labor, and arbitrary arrest and detention. Equal treatment of persons before the courts is guaranteed, and retrospective penal legislation is prohibited. Moreover, freedom of thought, conscience and religion are provided for, as are freedom of speech, assembly and association. G.A. Res. 2200 A, *supra* note 292, arts. 6, 7, 8, 9, 14, 15, 18, 19(2), 21, 22.

²⁹⁴ The Covenant provides for implementation at both the national and international levels. *Id.*, arts. 2(1), 28-45. Implementation at the national level has been criticized on the ground that Article 2 allows for States to postpone implementation by delaying the passage of legislation, as required by the Covenant under Article 2, which would assure the rights defined. The provisions for international implementation, contained in Articles 28-45, provide for creation of a human rights committee. Its functions are to deal with reports from States parties and to consider complaints by one State that another has not fulfilled its obligations. This procedure has been criticized as highly complicated and subject to long delays. In addition, neither the Human Rights Committee nor a Conciliation Commission, both of which are established by the Covenant, is empowered to make judicial determination. G.A. Res. 2200 A, *supra* note 292, arts. 41-42. See Humphrey, *supra* note 289, at 38-42. See generally Schwelb, *The International Measures of Implementation of the International Covenant on Civil and Political Rights and of the Optional Protocol*, 12 TEX. INT'L L.J. 141 (1977).

Regulation of experimentation could also be sought through the Optional Protocol to the Covenant, G.A. Res. 2200 A, *supra* note 292, arts. 1-2. A State party to the Covenant that is also a party to the Protocol recognizes the competence of the Human Rights Committee to receive and consider complaints from individuals who claim to be victims of violations by that State. However, the Committee is only permitted to forward its views to the State and the individual. *Id.* arts. 1-5. The Optional Protocol has been attacked on the grounds of providing a feeble enforcement mechanism and for failing to provide any means whereby third parties may bring complaints on behalf of individuals unable to bring them themselves. See Humphrey, *supra* note 289, at 44-48. Moreover, it is unlikely that creation of a new optional protocol will attract many adherents. See Bassiouni *The Prevention and Suppression of Torture*, *supra* note 33, at 108. See also Commission on Human Rights Draft Convention Against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment, U.N. Doc. E/CN.4/1367 (1980), reprinted in 19 INT'L LEGIS. MATERIALS 647.

²⁹⁵ European Convention, 213 U.N.T.S. 221 (Nov. 4, 1950) [hereinafter cited as 213 U.N.T.S. 221]. This Convention is regarded by some commentators as the most effective system yet created for the protection of human rights. Its great merit is that the individual is granted access to an international organ which can investigate his complaint, provided that

Convention may free itself from its obligations and from the decisions of the judicial bodies established thereunder²⁹⁶ by withdrawing from the Council of Europe and denouncing the Convention.²⁹⁷

the State concerned has subscribed to the "right of individual petition" and that before this right can be exercised, the individual must have exhausted local remedies. *Id.* art. 19. *See* D. PONCET, *LA PROTECTION DE L'ACCUSE PAR LA CONVENTION EUROPEENNE DES DROITS DE L'HOMME* (1977); A. ROBERTSON, *HUMAN RIGHTS IN EUROPE* (1977); Humphrey, *supra* note 289, at 49; Robertson, *Human Rights: A Global Assessment*, 53 *NOTRE DAME LAW.* 14, 23-24 (1977). One commentator has argued that the European Convention is gradually becoming integrated into the law of the member states of the European Community. Drzemczewski, *The Domestic Application of the European Human Rights Convention as European Community Law*, 30 *INT'L & COMP. L.Q.* 118 (1981). The effect of this development may be that the Convention will acquire persuasive force within the domestic courts of the member states, including those that have not "formally incorporated" it into their domestic law, when certain issues of European Community Law arise. *Id.* at 119. This does not necessarily mean, however, that a citizen of a member state has a remedy in that state's domestic courts for violations of the Convention by member states. *Id.* at 134-35.

²⁹⁶ At the international level, implementation is achieved primarily by two organs: the European Commission of Human Rights and a European Court of Human Rights. The Commission is essentially a conciliatory body, but it may also state its opinion that the facts disclosed to it reveal a violation of human rights on the part of a State party. Moreover, mere ratification of the Convention exposes a signatory to the possibility that another State will accuse it of a breach before the Commission. 213 U.N.T.S. 221, *supra* note 295, art. 24. *See* Humphrey, *supra* note 289, at 49.

²⁹⁷ The Greek government chose this course in 1967 and thereby opted out of its commitments regardless of the circumstances or the opinion of the world community when three Scandinavian governments and the Netherlands brought charges against the Greeks for violations of ten articles of the Convention. Had the Greeks not resigned and denounced the Conventions, they would have been expelled for their human rights violations. With the return of democracy, Greece ratified the Convention and was readmitted to the Council. Robertson, *supra* note 295, at 23.

For an analogy with the problems of torture and their implementation within the European Convention on Human Rights, *see* The Greek Case, [1972] Y.B. EUR. CONV. ON HUMAN RIGHTS 186 (Eur. Comm. on Human Rights); *Tyrer v. U.K.*, Application No. 5856/72, Report of the European Commission of Human Rights, 14 Dec. 1976; Requests No. 3321/67, 3323/67 et 3344/67, treated jointly in "L'Afaire Grecque," Strasbourg (1970). These cases are abstracted in an Amnesty International publication *TORTURE IN GREECE: THE FIRST FOUR TORTURERS' TRIAL* 1975 (1977). *See also* COUNCIL OF EUROPE, CONVENTION FOR THE PROTECTION OF HUMAN RIGHTS—CASE LAW TOPICS—HUMAN RIGHTS IN PRISONS 14 (1971); *Ireland v. United Kingdom*, 41 Collection of Decisions 3 (1972) (Eur. Comm. on Human Rights); Report of the Committee of Privy Counsellors (Cmno. 4901), minority report of Lord Gardiner, *Right of Self-Determination in International Law*, 8 *REV. INT'L COMM'N JURISTS* 44, 47 (1972). *See also* 28 U.S.C. § 1350 which grants United States District Courts original jurisdiction in "any civil action by an alien for a tort only, committed in violation of the law of nations or a treaty of the United States." *See* *Filartiga v. Pena-Irala*, 630 F.2d 876 (2d Cir. 1980) (permitting alien to sue agent of foreign government for torture); *see also* *Rosado v. Civiletti*, 621 F.2d 1179 (2d Cir. 1980) (describing practice of torture of persons under interrogation by Mexican police).

A potential difficulty in the European Conventions is that notified derogation is permitted in conditions of national emergency of such magnitude as to threaten the survival of the nation. 213 U.N.T.S. 221, *supra* note 295, art. 15, 213 U.N.T.S. at 232. While such a provision may be desirable in order to accommodate the needs of a State to perform its public duties for the common good, it is undesirable in the context of human experimentation since no reasonable need of the State could be served by suspension of such basic protective meas-

In the Western Hemisphere the leading human rights document is the American Convention on Human Rights.²⁹⁸ Although influenced by the European Convention, the former differs with respect to important features such as the definition of rights and procedures for implementation.²⁹⁹ However, the American Convention cannot be relied upon to enforce human rights because regional conventions on a worldwide scale demonstrate the lack of shared values and differences in legal systems among nations.³⁰⁰ In this respect regional conventions are too insufficiently specialized as to the human rights which they define and protect.

The Four Geneva Conventions of August 12, 1949,³⁰¹ provide the basic protection against unlawful human experimentation during war. The main thrust of these Conventions is to establish a humanitarian law of armed conflict which aims at protection of noncombatant military personnel and civilians who do not participate in the hostilities. Although the Geneva Conventions are primarily applicable to armed conflict,³⁰² provisions in each Convention expressly forbid the use of either protected military personnel or civilians for biological experimentation.³⁰³ Moreover, common article 3, which protects persons taking no active part in either international or non-international armed conflict, requires that all such persons be treated humanely. To this end, cruel, humiliating or degrading treatment is expressly prohibited. If such violations occur in the non-international context, the International Com-

ures as informed consent and peer review. Were such action taken, it is doubtful whether the common good would be served at all. See Higgins, DEROGATIONS UNDER HUMAN RIGHTS TREATIES, 1977 BRIT. Y.B. INT'L L. 281, 288-315.

²⁹⁸ O.A.S. Official Records OEA/Ser. K/XVI/1.1, Doc. 65, Rev. 1, Corr. 1 (Jan. 7, 1970), reprinted in 9 INT'L LEGAL MATERIALS 99 (1970).

²⁹⁹ One important difference is that the American Convention grants a right to persons, groups and non-governmental organizations to lodge petitions with the Inter-American Commission on Human Rights on behalf of others whose rights are allegedly violated. *Id.* arts. 44, 45. Thus, States which ratify the Convention become vulnerable to disputes with other States only if they expressly recognize the competence of the Commission to hear State applications. Humphrey, *supra* note 289, at 51-52. An Inter-American Court of Human Rights is also to be established, to which, however, individuals and organizations will not have access. American Convention, art. 61.

³⁰⁰ Lopez-Rey, *Crime and Human Rights*, 42 FED. PROB. 10, 12 (1978).

³⁰¹ Convention for the Amelioration of the Condition of the Wounded and Sick in Armed Forces of the Field, 75 U.N.T.S. 31; Convention for the Amelioration of the Condition of Wounded, Sick and Shipwrecked Members of Armed Forces at Sea, 75 U.N.T.S. 85; Convention Relative to the Treatment of Prisoners of War, 75 U.N.T.S. 135; Convention Relative to the Protection of Civilian Persons in Time of War, 75 U.N.T.S. 287.

³⁰² See Gulbrandsen, *A Commentary on the Geneva Conventions of August 12, 1949*, in INTERNATIONAL CRIMINAL LAW, *supra* note 5, at 368.

³⁰³ See generally J. PICTET, HUMANITARIAN LAW AND THE PROTECTION OF WAR VICTIMS (1975); I COMMENTARY: THE GENEVA CONVENTIONS OF 12 AUGUST, 1949, 370-72 (Pictet ed. 1952).

mittee of the Red Cross informs the party involved of the breaches committed and enjoins it to terminate such experiments. Violations which take place in this context constitute grave breaches of Article 50, of the First Convention, Article 51 of the Second Convention, Article 130 of the Third Convention and Article 147 of the Fourth Convention which prohibit *inter alia* biological experiments. For grave breaches the signatories are required to enact penal sanctions through domestic legislation. Article 12 of the First and Second Conventions, 12 of the Third, and 16, 27 and 32 of the Fourth provide that protected persons be treated humanely and in particular that they not be subject to ill treatment, biological, medical or scientific experiments regardless of their state of health, age or sex.

Of the 1977 Draft Additional Protocols Amending the Geneva Conventions of August 12, 1949, Protocols I and II provide protection for the investigator and further protections for the subjects. Article 11 of Protocol I prohibits medical or scientific experiments on protected persons even with their consent. Article 16(2) of Protocols I and II provide that medical personnel not be compelled to perform nor to refrain from performing medical activities "required by the rules of medical ethics." Article 12(1)-(2) of Protocol II provides that protected persons shall not be subjected to any medical procedure, particularly a medical or scientific experiment, which is not necessary for their health or which is contrary to accepted medical standards.

The Geneva Conventions and Protocols shift legal emphasis from military necessity to humanitarian considerations.³⁰⁴ Unethical experimentation on human subjects committed during armed conflict is clearly criminalized. Consequently, the interests of the individual assume great significance, and these interests supply the principles which should be adopted for the regulation of human experimentation relating to the context of peace.

Like the Geneva Conventions, the Crimes Against Humanity as defined by the Nuremberg Tribunal³⁰⁵ are related to the context of war,

³⁰⁴ van Dijk, *supra* note 289, at 1537.

³⁰⁵ Crimes Against Humanity are defined in Art. 6 of the Charter of the International Military Tribunal, annexed to the Agreement for the Prosecution and Punishment of the Major War Criminals of the European Axis, signed on August 8, 1945. 82 U.N.T.S. 279. These crimes include murder, extermination, enslavement, deportation and other acts of inhumanity committed against any civilian population, before or during World War II, or persecutions for political, racial, or religious reasons in execution of or connection with any crime within the jurisdiction of the Nuremberg Tribunal, whether or not in violation of the domestic law of the country where the crime was perpetrated. *See* INTERNATIONAL MILITARY TRIBUNAL, XXII TRIAL OF THE MAJOR WAR CRIMINALS BEFORE THE INTERNATIONAL MILITARY TRIBUNAL 496 (1947). On November 21, 1947, by Resolution 177 (II), the U.N. General Assembly directed the International Law Commission to enumerate the Principles of Nuremberg and to prepare a draft code of offenses against the peace and security of

and while elevating the interests of individuals above those of the military during armed conflict, the focus is on protection of whole populations rather than individuals.

Support for a specialized convention for protection of human subjects in peacetime is found in the Convention on the Prevention and Punishment of the Crime of Genocide.³⁰⁶ Although widely criticized as ineffectual despite ratification by the vast majority of countries,³⁰⁷ the Genocide Convention nevertheless protects certain groups of people rather than individuals.³⁰⁸ Genocide is defined as an international crime whether it is committed in time of war or peace (Article I). In particular, genocide is committed by any individual who causes bodily or mental harm to members of a national, ethnic, racial or religious group or by anyone who imposes measures intended to prevent births within such groups.³⁰⁹ Although it is reasonable to include unethical human experimentation among the criminal acts prohibited by these articles, the Genocide Convention is not sufficiently specific to adequately protect all human subjects. While the Convention would prohibit unethical experiments on protected groups, it would not safeguard against individual instances.³¹⁰ Therefore, even if the Genocide Convention does bar such experimentation, the scope of its protection is too narrow.

Finally, some support for a specialized convention is found in the Standard Minimum Rules for the Treatment of Prisoners and Related Recommendations.³¹¹ The Rules set forth standards for adequate medi-

mankind which incorporated those principles. For the history of the resolutions, see The Charter and Judgment of the Nuremberg Tribunal: History and Analysis, U.N. Doc. A/CN.4/5, at 11-33. Tornaritis, *The Individual as a Subject of International Law and International Criminal Responsibility*, in INTERNATIONAL CRIMINAL LAW *supra* note 5, at 103, 110-11; Bassiouni, *International Law and the Holocaust*, 9 CAL. W. J. INT'L L. 201 (1979).

³⁰⁶ U.N. GAOR Res. 96 (I), G.A. Res. 260 A (III), 78 U.N.T.S. 277 (Dec. 9, 1948).

³⁰⁷ Lopez-Rey, *supra* note 307, at 12. See generally P. DROST, THE CRIME OF STATE 119-36 (1959).

³⁰⁸ 78 U.N.T.S. 277 (1948). Article II defines the protected groups:

In the present Convention, genocide means any of the following acts committed with intent to destroy, in whole or in part, a national, ethnical, racial or religious group, as such:

- (a) Killing members of the group;
- (b) Causing serious bodily or mental harm to members of the group;
- (c) Deliberately inflicting on the group conditions of life calculated to bring about its physical destruction in whole or in part;
- (d) Imposing measures intended to prevent births within the group;
- (e) Forcibly transferring children of the group to another group.

³⁰⁹ *Id.*

³¹⁰ The scope of the Genocide Convention is not restricted to crimes committed in time of war. It is, therefore, part of the law of peace. Bassiouni, *Genocide and Racial Discrimination* in INTERNATIONAL CRIMINAL LAW, *supra* note 5, at 523; Woetzel, *War Crimes by Irregular and Nongovernmental Forces*, in INTERNATIONAL CRIMINAL LAW *supra* note 5, at 413.

³¹¹ E.S.C. Res. 663 C (XXIV), 31 July 1957. See also Note by the Secretary-General, The

cal care of prisoners, but are silent as to the use of prisoners as experimental subjects. Moreover, the Rules were passed as a U.N. resolution and consequently are only recommendatory.³¹² However, the Rules seek to advance the principle of asserting individual interests over those of prison authorities who may be unduly oppressive in their efforts to maintain order.

In summary, the existing legal environment defined by international human rights instruments provides a substantial basis for including experimentation within the human rights movement, but this framework is at present inadequate to meet the task of clearly defining the rights of subjects and the duties of investigators and states.

Additional support for a specialized convention can be drawn from consideration of customary international law and from general principles. The two documents which provide the strongest evidence for the existence of custom³¹³ are the Articles of the Nuremberg Tribunal and the Code of Ethics on Human Experimentation of the World Medical Association.³¹⁴ However, asserting the need for a convention may also imply that the essential elements of customary law—repeated usage and belief that a legal obligation has been fulfilled³¹⁵—may be lacking. Even if they are present, this general test is vague.³¹⁶ Adoption of a convention would mean removal of such ambiguities by creating clearly recognizable rights and unmistakably binding duties. Reliance upon general principles³¹⁷ is useful only to the extent that they are indicative of a legal policy or principle prevalent in all or most national legal sys-

Range of Application and the Implementation of the Standard Minimum Rules for the Treatment of Prisoners, U.N. General Assembly Provisional Agenda, Item 6, E/AC. 57/28, 24 May, 1976; Analytical Summary by the Secretary-General, Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment in Relation to Detention and Imprisonment, U.N. General Assembly Provisional Agenda, Item 75, A/10158, 23 July, 1975.

³¹² J. BRIERLY, *THE LAW OF NATIONS* 380-96, 413-32 (1963); I. BROWNIE, *PRINCIPLES OF PUBLIC INTERNATIONAL LAW* 14, 696 (1979).

³¹³ Two elements are required in order for custom to be considered a source of law. The first is a concrete element consisting of a repetition of action, sometimes called "usus". The second element is psychological in the sense that the repetitive action must be performed with the conviction that such performance fulfills a legal obligation or exercises a legal right. van Dijk, *supra* note 289, at 1541-43.

³¹⁴ See notes 52-66 & accompanying text *supra*.

³¹⁵ However, a convention may itself generate customary law, as did several of the conventions cited as to non-parties at Nuremberg. See generally A. D'AMATO, *THE CONCEPT OF CUSTOM IN INTERNATIONAL LAW* (1971).

³¹⁶ J. BRIERLY, *supra* note 312, at 61.

³¹⁷ General principles of international law refers to those principles which are found in all or most national legal systems and are therefore recognized by civilized nations. However, the term "civilized nations" is now regarded as obsolete since membership in the United Nations is universal and the notion that only certain States have monopolized civilization has been deflated. van Dijk, *supra* note 289, at 1544-46.

tems.³¹⁸ Accordingly, recourse to general principles leaves the issue of specificity unresolved. In short, the difficulty with both customary law and general principles is that neither is viewed as providing a sufficiently specific and binding source of law as compared to conventions.

National legal systems could also be considered as the exclusive measures for regulation of human experimentation. However, effective means of implementing these goals vary widely despite the recognition by most States that such achievement is desirable.³¹⁹

Besides the doctrinal foundation provided by the aforementioned sources of law, compelling policy reasons justify a specialized convention. These policies can be summarized as follows:

1. A convention would provide a clear and acceptable definition of experimentation which is sufficiently broad in scope to protect all human subjects.
2. It would apply to all contexts of human experimentation and extend universally to all States.
3. Individuals would be held accountable for violations, thereby avoiding conflict among the States.
4. A credible threat of punishment would be created by declaring certain acts to be international crimes.
5. A duty would be created on all signatory States to prosecute or extradite.
6. Maximum international attention would be focused on a State for refusal to carry out its obligations.
7. A convention would provide a modicum of international implementation through use of existing enforcement mechanisms.
8. It would reinforce and strengthen the resolve and ability of individuals and States attempting to secure greater protection of human subjects without placing unreasonable duties on them or causing undue embarrassment to States willing to comply with the convention.
9. The scientific community would continue to enjoy adequate protection while those of subjects would be increased.
10. A convention would provide more extensive control than is provided by municipal legal systems alone.

Reasons of policy strongly favor protection of human subjects through international law, and a specialized convention offers the most effective approach.³²⁰ Human experimentation must be singled out be-

³¹⁸ J. BRIERLY, *supra* note 312, at 63; I. BROWNLIE, *supra* note 312, at 15-19. For a discussion of the role of international conventions (especially the International Covenant on Civil and Political Rights) in codifying certain general principles of the world's legal systems and therefore as binding states which have not ratified those instruments, see Havener & Mosher, *General Principles of Law and the U.N. Covenant on Civil and Political Rights*, 27 INT'L & COMP. L.Q. 596 (1978).

³¹⁹ See THE PREVENTION AND SUPPRESSION OF TORTURE, *supra* note 33, at 107.

³²⁰ There is ample precedent for this approach as evidenced by the following international instruments:

1. 1948 Genocide Convention

cause the reinforcement of general human rights prescriptions will not lead to the protection of human subjects. The basic elements of such an approach are, first, to strengthen the effectiveness of national control systems. These systems should then be supported by an international obligation to carry out those controls. The expectation that such a system will be acceptable to the world community is based on extensive international cooperation in scientific endeavors³²¹ and the relatively insensitive political nature of human experimentation.³²²

Although violations of human rights continue to be widespread³²³ and are a source of discouragement to human rights advocates,³²⁴ there is evidence of increasing acceptance by governments, nongovernmental organizations and individuals of the obligation to respect human rights.³²⁵ Grimly conscious that the atrocities of World War II are a threat to the peace and security of all, the states of the world must acknowledge the practicality inherent in the development of the human rights movement. A convention which singles out human experimentation and the rights of research subjects as a specific area for protection is appropriately intended as part of this program.

VIII. CONCLUSION

By the end of World War II when the London Charter of August 8, 1945,³²⁶ was agreed upon for the prosecution of major war criminals, the framework for such prosecutions was defined within the parameters of the laws of war, namely war crimes. The laws of war were at that time

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2. 1961 Single Convention on Narcotic Drugs
 3. 1972 Amending Protocol to the 1961 Single Convention on Narcotic Drugs
 4. 1971 Convention on Psychotropic Substances
 5. Four Geneva Conventions of 12 August 1949
 6. 1973 Draft Additional Protocol to the Geneva Conventions
 7. 1963 Tokyo, 1970 Hague, and 1971 Montreal Conventions on Aircraft Hijacking
 8. 1973 Convention on Kidnapping of Diplomatic Personnel.

See Bassiouni, *supra* note 90, at 423. Dinstein, *supra* note 81, at 166-67.

³²¹ See notes 282-83 & accompanying text *supra*.

³²² Compare, for example, the numerous United Nations resolutions of the General Assembly, Security Council and other organs condemning the policies of apartheid with its pronounced political overtones. See ACTION, *supra* note 290, at 41-46. There are also strong political elements with respect to the abolition of torture since it, like apartheid, is practiced as government policy. See Bassiouni, *The Prevention and Suppression of Torture*, *supra* note 33, at 106-07.

³²³ See Robertson, *Human Rights* *supra* note 295, at 15-17; Lopez-Rey, *supra* note 300, at 12.

³²⁴ See van Dijk, *supra* note 289, at 1552-53.

³²⁵ See Higgins, *supra* note 289, at 12-13; Humphrey, *supra* note 289, at 60-61; van Dijk, *supra* note 289, at 1552-53; Robertson, *Human Rights* *supra* note 295, at 32. See also Rodley, *Monitoring Human Rights by the U.N. System and Nongovernmental Organizations in HUMAN RIGHTS AND AMERICAN FOREIGN POLICY* (D. Kommers & G. Loescher eds. 1979).

³²⁶ Agreement for the Prosecution and Punishment of the Major War Criminals of the European Axis, 8 August 1945, 82 U.N.T.S. 279.

defined in the Hague Conventions of 1907,³²⁷ which codified the customary laws of war and the Geneva Convention of 1864,³²⁸ as amended in 1929.³²⁹ Crimes against humanity were new crimes which, though related to war, had at that time no substantive legal basis. The Nuremberg prosecutions and judgments confirmed the separateness of war crimes and crimes against humanity, though the acts falling under the two definitions created an overlap. Thus human experimentation, if conducted against prisoners of war and civilian populations under military occupation, would be a war crime, while such experiments on a state's own population would be a crime against humanity, provided, however, that they are performed in the context of war.

The General Assembly's Declaration on the Principles of the Nuremberg Charter and Judgment³³⁰ restated the essence of the Nuremberg indictments, trials and judgments in the form of concise principles in order that they would serve as a reliable and ascertainable historical precedent. Nevertheless, the resolution maintains the distinction necessitated by the manner in which the London Charter set forth the charges of the prosecution and, consequently, conditioned the outcome. It is, therefore, clear that the General Assembly principles create the same overlap and leave the same gap that exists under the Nuremberg trials. To bridge that gap between the law of war and the law of peace and to ensure the application of international criminal law to certain abhorrent acts which shock the universal conscience, the Genocide Convention was elaborated. It prohibits the use of unlawful human experimentation but only in the context of genocide. Only the wholesale use of human subjects for experimental purposes performed with the intent to exterminate a given people is encompassed therein.

³²⁷ Hague Conventions of 18 October 1907:

No. III, Relative to the Opening of Hostilities, 3 MARTENS NOUVEAU RECUEIL (3rd) 437.

No. IV, Respecting the Laws and Customs of War on Land, 3 MARTENS NOUVEAU RECUEIL (3rd) 341.

Annex to Hague Convention No. IV of 18 October 1907, embodying the Regulations Respecting the Laws and Customs of War on Land, 2 SCOTT, HAGUE PEACE CONFERENCE 376.

No. V, Respecting the Rights and Duties of Neutral Powers and Persons in Case of War on Land, 3 MARTENS NOUVEAU RECUEIL (3rd) 504.

No. IX, Concerning Bombardment by Naval Forces in Time of War, 3 MARTENS NOUVEAU RECUEIL (3rd) 604.

No. X, for the Adaptation to Maritime Warfare of the Principles of the Geneva Convention, 3 MARTENS NOUVEAU RECUEIL (3rd) 630.

³²⁸ Geneva Convention for the Amelioration of the Condition of the Sick and Wounded of Armies in the Field, 22 August 1864, 18 MARTENS NOUVEAU RECUEIL DES TRAITES (1st) 607.

³²⁹ Geneva Convention for the Amelioration of the Condition of the Wounded and Sick in Armies in the Field, 27 July 1929, 118 L.N.T.S. 303.

³³⁰ Report of the International Law Commission, 5 U.N. GAOR, Supp. (No. 12) 11-14 U.N. Doc. A/1316 (1950).

Subsequent to 1948, human rights conventions have proscribed cruel, unusual and degrading treatment and punishment, but have not dealt specifically with the issue of human experimentation (except for Article 7 of the Covenant on Civil and Political Rights), even though it presumably could be deemed to fall within the scope of the proscriptions referred to above. In addition, the concept of unlawful human experimentation re-enters the law of peace by analogy to the prohibitions against torture, except that experiments could be privately performed and not be for the purpose of obtaining a statement. There is, however, no clear definition of what unlawful human experimentation means or encompasses. Nor is there any specific requirement that States ensure against such practices by effective means of prevention and suppression.

One may confidently conclude that the laws of war under the Geneva Conventions prohibit human experimentation but lack adequate definition. The general principle of "crimes against humanity," which could also be labelled a customary principle, encompasses these acts, provided they are war-related, but does so without any definition or specificity as to the content of the prohibition. Moreover, the Genocide Convention limits its content. Finally, the human rights covenants generally encompass human experimentation only within the broad meaning of cruel, unusual and degrading treatment and punishment, but this is done without definitional content and without considering the implementation of criminal sanctions or administrative mechanisms against such acts. It is apparent, therefore, that the elaboration of three documents is warranted: (1) an international convention for the prevention and suppression of unlawful human experimentation; (2) a set of draft principles for the international regulation of human experimentation; and (3) guidelines for national legislation concerning human experimentation.³³¹ Their mission is to define human experimentation, the parameters of its lawfulness, and the nature of unlawful acts. The obligation of states to regulate their activities in order to prevent and suppress unlawful conduct and to express the universal human concern with a category of activities whose potential for abuse is revealed by history and the uncertainties of modern medical science and technology is uncontested. Although no abuses have been committed by any state which are comparable to those of World War II, such regulation would truly be preventive and, thus, fulfill one of the long sought-after yet seldom attained goals of law in general and of international law in particular.

³³¹ An international regulatory scheme comprised of three such documents was recently proposed following discussions among an international committee of experts sponsored by the International Institute for Higher Studies in Criminal Sciences, Siracusa, Sicily, from May 24 to June 1, 1980. See *Étude Générale*, 51 REVUE INT'IE DE DROIT PÉNAL 357 (1981).