
The Treating Physician As Researcher: Is Assuming This Dual Role A Violation Of The Nuremberg Code?

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I. INTRODUCTION

On August 15, 1947, the International Military Tribunal formulated the Nuremberg Code in response to the atrocities that the Nazis perpetrated, in the name of science, in concentration camps during World War II.¹ The Nuremberg Code represented the foundation for the ethics of human medical research.² In the first trial conducted by the Military Tribunal after the war, the defendants were twenty-three Nazis accused of conducting medical experiments on concentration-camp inmates.³ Often, these experiments resulted in death or mutilation. The Tribunal accused these defendants of murder and torture. Twenty of the twenty-three defendants were doctors. These individuals were well-educated, and some were renowned scientists prior to the war. At the conclusion of the trial, sixteen

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¹ GEORGE J. ANNAS & MICHAEL A. GRODIN, *THE NAZI DOCTORS AND THE NUREMBURG CODE* 4 (Oxford Univ. Press 1992).

² *Id.*

³ See generally *Introduction to Nuremberg Military Tribunal Case 1, U.S.A. v. Karl Brandt et al.*, THE NUREMBURG TRIAL PROJECT, HARVARD LAW SCHOOL LIBRARY (2003), http://nuremberg.law.harvard.edu/php/docs_swi.php?DI=1&text=medical (last visited Oct. 1, 2006) [hereinafter *Nuremberg Case 1*] (providing background information serving as an introduction to an online collection of thousands of documents relating to the Nuremberg Military Tribunal trials).

defendants were found guilty and seven executed. The Tribunal then set forth the Nuremberg Code, which provided guidelines for ethical medical research.⁴

This code empowers the subject in human research to decide whether or not to participate. Informed consent is an absolute requirement.⁵ No longer is the physician/researcher the exclusive guide to research ethics, nor is the Hippocratic Oath⁶ the sole protection of human research subjects. The subject's free will to give informed consent is an additional protection of the individual.⁷ Given the Nazi experimentations, it is clear that society cannot rely on physicians/researchers to self-regulate and pursue research ethically. The physician's tenant of "do no harm" does not apply to research in the same manner as it does to treatment.⁸ Human rights protection in medical research is woefully inadequate. As history all too frequently demonstrates, society cannot rely solely on the conscientious, ethical researcher to protect human research subjects.

This article will examine the factors involved in medical research, particularly the aspect of informed consent as applied to research performed by physicians. The issue of major concern will be the subject's ability to give truly informed consent in situations where the treating physician assumes the dual role of researchers. This article will ask if physicians can assume this dual role without violating the Nuremberg Code; and whether individuals can be both subjects and patients without sacrificing their free will and autonomy. This article will argue that the tensions in these dual roles are at odds with the fundamental values of law and society, and that current federal regulation and judicial remedies are inadequate to protect research subjects. This article proposes a *per se* rule that prohibits treating physicians from assuming the dual role of researcher. Society must reassess its values to protect individual subjects, but also allow science and medicine to progress. Above all, society should never allow individuals to be treated merely as means to an end, or allow researchers "to treat their fellow human beings as less than beasts."⁹

Part I of this article will explore the importance of informed consent and its basis in law and society. Part II will discuss the definition of informed consent and its legal implications. Part III will analyze the history of informed consent, its abuses, and the judiciary's legal responses. Part IV will explore the problems with the current legal requirements for informed consent in medical investigation and will suggest changes that will satisfy the requirements of the Nuremberg Code.

⁴ *Id.*

⁵ NUREMBERG CODE, in *United States v. Karl Brandt (Doctors' Trial)*, 1 *Trials of War Criminals before the Nuremberg Military Tribunals Under Control Council Law No. 10*, Vol. 2, 181-82 (1950) [hereinafter *Nuremberg Code*].

⁶ See generally THE HIPPOCRATIC OATH: TEXT, TRANSLATION AND INTERPRETATION (Ludwig Edelstein trans., Johns Hopkins Press 1943) (embodying the beneficence of physicians).

⁷ *Nuremberg Code*, *supra* note 5, at 181-82.

⁸ NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH, 44 Fed. Reg. 23,192, 23,195 (Apr. 18, 1979) [hereinafter *Belmont Report*].

⁹ Evelyn Shuster, *Fifty Years Later: The Significance of the Nuremberg Code*, 337 NEW ENG. J. MED. 1436, 1437 (1997) (quoting *Complete Transcript of the Nuremberg Medical Trial: United States v. Karl Brandt et al. (Case 1)*, Washington, D.C.: National Archives, November 21, 1946-August 20, 1947).

PART I. THE IMPORTANCE OF INFORMED CONSENT AND ITS BASIS IN OUR LAW AND SOCIETY

The requirement of informed consent prior to medical treatment or investigation allows for individual autonomy and self-determination.¹⁰ These values are fundamental in society and government.¹¹ The interest of society cannot be placed above individual freedoms unless an overriding state interest exists.¹² It is unacceptable to sacrifice the rights of one individual for the benefit of others, or the benefit of society as a whole.¹³ As a society, we do not embrace utilitarian principles, but instead we believe that liberty, autonomy, and self-determination should guide law and society.¹⁴ The preamble of the United States Constitution stresses liberty.¹⁵ The Fourth and Fourteenth Amendments of the US Constitution establish individual rights and exemplify the fundamental importance of individual autonomy in society, government, and history.¹⁶

The United States Supreme Court generally upholds the fundamental rights of individual autonomy and self-determination. The Court recognized the pregnant woman's right of autonomy in *Planned Parenthood of Southeastern Pennsylvania v. Casey*¹⁷ and in *Thornburg v. American College of Obstetricians and Gynecologists*.¹⁸ In the "right to die" cases, *Washington v. Glucksberg*¹⁹ and *Cruzan v. Director, Missouri Department of Health*,²⁰ the Court recognized autonomy and self-determination as fundamental rights. The Court created a notable exception to the protection of individual rights in the military context. In *United States v. Stanley*,²¹ the majority found that the LSD experiments, conducted by the military with soldiers as un-informed subjects, were not open to judicial intrusion.²² Justice Brennan dissented, stressing the violation of individual rights. Brennan argued that, without a showing of an overriding governmental interest, these experiments could not be

¹⁰ *Schloendorff v. Society of New York Hospital*, 105 N.E. 92, 134-35 (N.Y. 1914).

¹¹ WILLIAM BLACKSTONE, 1 COMMENTARIES *125 (providing that "[t]he absolute rights of man, considered as a free agent, endowed with discernment to know good from evil, and with power of choosing those measures which appear to him to be most desirable, are usually summed up in one general appellation, and denominated the natural liberty of mankind"); Kendall Ann Desaulniers, *Legislation to Protect the Decisionally Incapacitated Individual's Participation in Medical Research: Safety Net or Trap Door?*, 13 REGENT U.L. REV. 179, 215 (2000) (quoting BLACKSTONE).

¹² *Lawrence v. Texas*, 539 U.S. 558, 578 (2003).

¹³ U.S. CONST. amend. I-X.

¹⁴ *Id.*

¹⁵ U.S. CONST. pmbi.

¹⁶ U.S. CONST. amend. IV, XIV.

¹⁷ 505 U.S. 833, 851-52 (1992) (balancing the pregnant woman's right to autonomy against the rights of an unborn fetus).

¹⁸ 476 U.S. 747, 781 (1986) (Stevens, J., concurring) (defending a woman's right to abortion, arguing that "it is far better to permit some persons to make incorrect decisions than to deny all individuals the right to make decisions that have a profound effect upon their destiny").

¹⁹ 521 U.S. 702, 719-20 (1997) (criminalizing physician assisted suicide, but recognizing the individual's right to die).

²⁰ 497 U.S. 261, 278-81 (1990) (accepting the patient's right to refuse medical treatment).

²¹ 483 U.S. 669, 683-84 (1987).

²² *Id.* at 686 (considering the issue "a question of military discipline and decision making").

justified.²³

In United States history and in current society, autonomy and self-determination are guiding principles. The regulation of potentially dangerous activities and social funding illustrate their importance.²⁴ The choice of whether or not to engage in hazardous activities belongs to the individual. While the state or federal government may require disclosure or regulation of certain risks, the government does not proscribe dangerous activities. Granted, some legislation is paternalistic, but only when a governmental interest overrides the individual's right to autonomy.²⁵ Society allows individuals to make lifestyle decisions, such as choices about whether or not to seek health care. One is free to undergo or to refuse treatment for disease or injury, even if such a decision results in death.²⁶ After examining history and current law, it is clear that autonomy and self-determination are highly valued and fundamental rights in the United States.

The advancement of medical knowledge, specifically in scientific investigation, is not a fundamental right in our society. While the federal government spends money to spur medical research, neither funding nor scientific research is a recognized right. In fact, federal funding spurs federal regulation to limit research to comply with current ethical and legal standards.²⁷ Congress, through the Department of Health and Human Services, further restricts research under the Commerce Clause's authority.²⁸ Congress can thus regulate all experiments involving medical devices or drugs not yet approved by the FDA,²⁹ regardless of who funds the investigation. The right to experiment is not automatic. This right must be earned by following the appropriate federal regulations, which are an attempt to protect individual subjects physically and to preserve their free will and autonomy. This situation is different than the rules governing the fundamental rights of self-determination and autonomy, which are automatic, unless an opposing, compelling governmental interest exists.

PART II. THE DEFINITION OF INFORMED CONSENT AND ITS LEGAL IMPLICATIONS

To give informed consent, the individual must be in a position to freely agree to the suggested course of action. The *Belmont Report*, a federal commission summarizing the basic ethical principles underlying medical research involving human subjects, lists the requirements of informed consent as information, comprehension, and voluntary assent.³⁰ Black's law dictionary defines informed consent as "a person's agreement to allow something to happen (such as surgery) that

²³ *Id.* at 708 (Brennan, J., dissenting) (noting that "[s]oldiers ought not be asked to defend a constitution indifferent to their essential human dignity").

²⁴ For example, although smoking is detrimental to individual health, it is still legal to manufacture, to sell, and to use tobacco products. Additionally, playing dangerous sports, riding motorcycles, and consuming alcohol are all legal, despite the definite risks these activities pose to individuals.

²⁵ *Washington v. Glucksberg*, 521 U.S. 702, 724 (1997).

²⁶ *Cruzan*, 497 U.S. at 279.

²⁷ 45 C.F.R. § 46 (2005) [hereinafter *Common Rule*] (providing rules for federally funded experimentation involving human subjects).

²⁸ 21 C.F.R. § 50, 56 (2001) [hereinafter *FDA Regulation*] (providing federal rules governing research involving experimental drugs or medical devices).

²⁹ *Id.*

³⁰ *Belmont Report*, *supra* note 8.

is based on a full disclosure of facts needed to make the decision intelligently; i.e., knowledge of risks involved, alternatives, etc.”³¹ For a patient/subject to agree to a course of action requires that he or she understand the implications of pursuing that action. One must understand to be informed.

The frequent assumption that mere disclosure fulfills the understanding requirement of informed consent is incorrect. The disclosure of a consent form, for either treatment or research, only pays lip service to the necessity of understanding. A physician who merely recites a list of risks, benefits, and alternatives does not aid the patient in understanding. Informed consent cannot be a passive process, and requires that the subject be an active participant in the decision to undergo a course of treatment or scientific study.³² Active participation requires that the individual patient/subject is able to manipulate information relevant to the treatment or study, so that he or she can predict the consequences of participation. For a research participant to be truly informed, he or she cannot rely on the advice or suggestions of the investigator without understanding the implications of participating (or refusing to participate) in the study.³³

The federal regulations do not address the process of obtaining informed consent, nor does it define informed consent.³⁴ The rule does outline the eight requirements of informed consent necessary for federally funded research.³⁵ Informed consent in research must be fully informed, a stricter standard than required in treatment.³⁶ In research, the subject’s decision is whether or not to participate in an experiment with an unknown outcome. This uncertainty makes the requirement of fully informed consent critical. The risk that subject takes is not wholly for the subject’s benefit. Understanding is dependent on the subject, not the investigator alone. While disclosure by the investigator is required, comprehension by the subject is essential.³⁷ This article will explore the requirements of understanding and voluntariness in obtaining informed consent.

A. Understanding:

The judiciary addressed the requirement of understanding in the context of both patient research and treatment. The history of informed consent in treatment is based predominantly in the common law, whereas the history of law regarding

³¹ BLACK’S LAW DICTIONARY 779 (6th ed. 1990) (defining consent as “an act of reason, accompanied with deliberation, the mind weighing as in a balance the good or evil on each side. It means voluntary agreement by a person in the possession and exercise of sufficient mental capacity to make an intelligent choice to do something proposed by another. It supposes a physical power to act, a moral power of acting, and a serious, determined, and free use of these powers. Consent is implied in every agreement. It is an act unclouded by fraud, duress, or sometimes even mistake”).

³² T.H. Moseley et al., *Effects of presentation method on the understanding of informed consent*, 90(8) BRIT. J. OPHTHALMOLOGY 990 (2006).

³³ OFFICE FOR PROTECTION FROM RESEARCH RISKS, TIPS ON INFORMED CONSENT, available at <http://www.hhs.gov/ohrp/humansubjects/guidance/ictips.htm> (last visited Oct. 20, 2006).

³⁴ General Requirements for Informed Consent, 45 C.F.R. § 46.116.

³⁵ *Id.*

³⁶ *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 483-85 (Cal. 1990).

³⁷ See generally *Moore*, *supra* note 36, at 483-85 (finding that doctors breached their duty of informed consent by not disclosing their intent to use patients’ cells for medical research).

research is predominantly statutory. The requirement of informed consent in treatment evolved from early cases regarding the law of battery. The plaintiff's advantage in battery claims was that injury was not required for a successful suit; the only requirement necessary was un-consented touching by the physician.³⁸ In *Schloendorff v. Society of New York Hospital*, the Court of Appeals of New York established the reasonable physician standard as the standard for disclosure.³⁹ This standard allowed physicians to determine the amount of information to disclose. Under this standard, patients relied on the beneficence of physicians to act in their best interest. In effect, this standard permitted physicians to hide behind their professionalism.⁴⁰ Physicians, as a group, controlled the dissemination of their specialized knowledge and expertise.⁴¹ Patients could not determine what information might enable them to make an informed decision regarding treatment.⁴²

The standard required for disclosure in medical treatment evolved to the reasonable patient standard in many jurisdictions. The standard became firmly established in *Canterbury v. Spence*.⁴³ The standard required the disclosure of all information material to the reasonable patient's decision.⁴⁴ The United States District Court for the District of Columbia reasoned that the predominant issue was what was important to the patient, not what was important to physicians. Otherwise, the physician could remain in control and withhold facts essential to the patient's decision. In this manner, physicians could manipulate decision-making by patients and restrict patient autonomy. The paramount issue was not whether or not the patient consents, but the physician's manipulation of the process. The *Canterbury* court briefly discussed, but dismissed, the subjective patient rule, finding that this standard would leave physicians without any guidance.⁴⁵ Under the subjective patient rule, doctors could not anticipate the correct information to disclose. Patients who experienced bad outcomes could easily argue that they would not have consented to the treatment if their doctors had told them "X, Y, Z." This standard could potentially open the floodgates on litigation, leaving physicians at the mercy of their patients.

For a cause of action for the violation of informed consent, it is required that the patient suffered harm. The patient must then show that, if the risk were disclosed and understood, he or she would not undergo treatment. There are exceptions to the requirement of informed consent in medical treatment, such as for therapeutic

³⁸ *Trogon v. Fruchtman*, 207 N.W.2d 297, 310-11 (Wis. 1973).

³⁹ 105 N.E. 92, 134-35 (N.Y. 1914).

⁴⁰ See Frank M. McClellan, *Informed Consent to Medical Therapy and Experimentation*, 3 J. LEGAL MED., 81, 82-83 (1982) (physicians that mastered complex material decided they were best able to make critical decisions regarding their patients in the Tuskegee experiment instead of giving consideration to their individual patients).

⁴¹ See *id.* at 81-97 (giving examples of studies in which physicians have controlled disclosure to the detriment of the patients and discussing the effects of professionalism on disclosure).

⁴² See *id.* (detailing the consent issues present when subjects of an experiment were denied the knowledge both that they were subjects of an experiment, and that they had syphilis. These subjects were unable to request the penicillin necessary to cure syphilis, being unaware of their condition).

⁴³ 464 F.2d 772, 786-787 (D.C. Cir. 1972).

⁴⁴ *Id.*

⁴⁵ *Id.* at 790-791.

privilege⁴⁶ and emergency. However, these exceptions are necessarily limited so as not to swallow the rule.

The requirement of informed consent in research initially followed the common law rule of informed consent in treatment.⁴⁷ This choice should solely be the subject's decision.⁴⁸ Part IV of this article will further explore this proposition in connection with the interest and intent of the parties. Early case law suggested that any deviation from the standard practice of treatment constituted negligence, regardless of whether or not informed the physician obtained informed consent.⁴⁹ The courts spurned experimentation; therefore, any deviation from accepted practice put the doctor at risk.⁵⁰

Some courts began to accept deviation in the interest of advancing medical knowledge. In *Fortner v. Koch*⁵¹ the Supreme Court of Michigan noted that "if the general practice of medicine and surgery is to progress, there must be a certain amount of experimentation carried on; but such experiments must be done with the knowledge and consent of the patient . . . and must not vary too radically from the accepted method or procedure."⁵² Later courts applied the standard for malpractice negligence to informed consent in research.⁵³ The amount of required disclosure depended on the jurisdiction's standard for medical malpractice. This standard was either the reasonable patient or the professional standard. In *Whitlock v. Duke University* the United States District Court for the Middle District of North Carolina adopted a stricter standard of disclosure for non-therapeutic research.⁵⁴ The court required disclosure of all reasonable foreseeable risks.⁵⁵ In *Human Experimentation and Human Rights*, Jay Katz suggested that the required standard should be the full, informed consent of the reasonable subject.⁵⁶

⁴⁶ Molson Medical Informatics Site on Biomedical Ethics & Law in Clinical Practice, <http://sprojects.mmi.mcgill.ca/ethics/definitions.htm> (last visited September 7, 2006) ("therapeutic privilege (therapeutic exception) [is] a rare situation, in which the physician may be excused from disclosing information to a patient when there is sufficient evidence that the patient is not psychiatrically or emotionally stable to handle the information, that the disclosure of information itself would pose serious and immediate harm to the patient, such as inducing some physiologic response such as a heart attack or prompting suicidal behavior").

⁴⁷ See Jesse A. Goldner, *An Overview of Legal Controls on Human Experimentation and the Regulatory Implications of Taking Professor Katz Seriously*, 38 ST. LOUIS U. L.J. 63, 71-87 (1993) (reviewing the history of case law on informed consent).

⁴⁸ See Karine Moran, *The Standard of Disclosure in Human Subject Experimentation*, 19 J. LEGAL MED. 157, 221 (1998) (concluding that "[o]nly a distinct and strict rule on full disclosure can protect the principle of autonomy of human research subjects...").

⁴⁹ *Jackson v. Burnham*, 39 P. 577, 580 (Colo. 1895) ("if a physician sees fit to experiment with some other mode, he should do so at his peril").

⁵⁰ See generally ARNOLD J. ROSOFF, *INFORMED CONSENT A GUIDE FOR HEALTH CARE PROVIDERS* (1981) (noting judiciary's distaste for experimentation without informed consent).

⁵¹ 261 N.W. 762, 765 (Mich. 1935).

⁵² *Id.*

⁵³ *Gaston v. Hunter*, 588 P.2d 326, 350 (Ariz. Ct. App. 1978) ("in malpractice, the duty of the physician to disclose is determined by the normal practices of his profession in the particular community"). In this case, the court does not attempt to differentiate experimental or novel procedures from standard treatment.

⁵⁴ 637 F. Supp. 1463, 1471 (M.D.N.C. 1986), *aff'd*, 829 F.2d 1340 (4th Cir. 1987).

⁵⁵ *Id.* at 1471-72.

⁵⁶ Jay Katz, *Human Experimentation and Human Rights*, 38 ST. LOUIS U. L.J. 7, 34-35 (1993).

Thereafter, the assumption that only medical or research experts could determine what was adequate disclosure ended in many jurisdictions. While experts or professionals are required to determine the scientific appropriateness of the investigation, they are not in a position to determine the adequacy of disclosure to the subject.⁵⁷ The Nuremberg Code, *Canterbury* and *Moore* stated this change.⁵⁸ In *Moore*, the patient underwent a splenectomy, believing that operation's only purpose was treatment.⁵⁹ However, the physician used the cells from his spleen to create a cell line and monoclonal antibodies,⁶⁰ but never disclosed these experimental aspects to Moore.⁶¹ The physician/investigator benefited economically and professionally.⁶² The Supreme Court of California found a fiduciary duty in the doctor-patient/researcher-subject relationship.⁶³ As a result, the court ruled that the physician breached his duty of informed consent and of his duty to disclose all material facts in obtaining consent.⁶⁴ These material facts included any economic benefit and personal interests to the investigator.⁶⁵

In a similar Canadian case, the court ruled that the information provided to a research subject was inadequate to constitute informed consent.⁶⁶ While the subject believed that the experiment's risks were minimal, in truth, the risks were unknown. The researchers informed the subject that he would only be injected with a needle in his arm. The subject was not told that he would undergo heart catheterization. The court differentiated the standard of disclosure in medical experimentation from that in treatment, stating that "the subject . . . is entitled to a full and frank disclosure of all the facts, probabilities and opinions which a reasonable man might be expected to consider before giving his consent."⁶⁷ The *Halushka* court concluded that the information provided was inadequate for the subject to make an informed decision regarding whether to participate in the experiment.⁶⁸

These sporadic tort cases reflecting inadequate disclosure and failure to fulfill the requirement of patient understanding gave way to international codes and federal regulations. However, the case law for failure to fulfill the requirements of informed consent remains sparse in both federal and state courts. This article will outline the evolution of regulatory control in Part III: Responses to Abuses.

⁵⁷ See *id.* (discussing the information that doctors should give patients when obtaining informed consent.); See also *Goldner*, *supra* note 47, at 88 (involving human experimentation and informed consent).

⁵⁸ *Nuremberg Code*, *supra* note 5, at 181-82; *Canterbury*, 464 F.2d at 786-787; *Moore*, 793 P.2d at 481-85. This shift presented an inherent problem in the current make-up of Institutional Review Boards, which the article will address below.

⁵⁹ *Moore*, 793 P.2d at 481.

⁶⁰ *Id.*

⁶¹ *Id.* at 483.

⁶² *Id.* at 482.

⁶³ *Moore*, 793 P.2d at 485.

⁶⁴ *Id.*

⁶⁵ *Id.*

⁶⁶ *Halushka v. Univ. of Saskatchewan*, [1965] 52 W.W.R. 608, 609-611 (Can).

⁶⁷ *Id.* at 617.

⁶⁸ *Id.*

B. Voluntariness:

The requirement that consent be voluntarily given does not receive much judicial attention. This principle of voluntary consent flows from the rights of autonomy and self-determination, and is analogous to tort principles and the requirements against coercion and overreaching.⁶⁹ The Nuremberg Code stresses the voluntary requirement of informed consent, as does the *Belmont Report*.⁷⁰ Ethical literature and law reviews discuss the effect of the researcher-subject relationship.⁷¹ This relationship can dramatically affect the ability of individuals to act in a voluntary manner. Relationships often change the manner in which individuals make decisions and interpret information. When someone we trust suggests a course of action, the resulting decisions are not entirely self-determined because we assume the other person has our best interests in mind.

This article will not discuss experiments conducted on designated vulnerable populations in detail, but simply analogize patients as vulnerable subjects. Studies performed on prisoners,⁷² the mentally ill,⁷³ the chronically ill,⁷⁴ and children⁷⁵ violate the subject's ability to give informed consent. These subjects are in a position of coercion or overreaching. Perhaps these subjects feel as though they could not refuse to participate in research. Consequently, their decision to participate in research is not voluntary. The unequal footing of knowledge between physician/investigator and patient/subject, along with the patient's reliance on physician's beneficence, makes the patient a vulnerable subject.⁷⁶ An ill or dying patient is easily vulnerable to the promise of an experimental treatment, particularly when his or her treating physician suggests participation. The patient's assent in such a situation is prejudiced and not truly voluntary. Patients, used as subjects, often interpret the suggestion of research participation as a treatment

⁶⁹ 45 C.F.R. § 46.116 (2005).

⁷⁰ See *Nuremberg Code*, *supra* note 5 (defining voluntary consent as requiring that the person have legal capacity to consent, the power of free choice, and the sufficient knowledge and understanding necessary to make an informed decision); *Belmont Report*, *supra* note 8 (discussing what makes consent voluntary, specifically that the decision must be made free from coercion and undue influence).

⁷¹ See JAY KATZ ed., *EXPERIMENTATION WITH HUMAN BEINGS* 323-434 (Russell Sage Foundation 1972) [hereinafter *Katz on Experimentation*] (a compilation of articles and cases discussing the consequences of research to subjects and how these consequences should affect the authority of the investigator); Karine Morin, *The Standard of Disclosure in Human Subject Experimentation*, 19 J. LEGAL MED. 157, 216-218 (1998) (describing the researcher-subject relationship and how it differs from the doctor-patient relationship, despite the fact that both have been described as fiduciary); Franklin G. Miller, *Professional Integrity in Clinical Research*, 280 J. AM. MED. ASS'N. 1449, 1452-1453 (1998) (discussing the relationship between physician investigators and patient research volunteers and the conflicting positions that both parties find themselves in with respect to having both a doctor-patient and a researcher-subject relationship).

⁷² ALLEN M. HORNBLUM, *ACRES OF SKIN: HUMAN EXPERIMENTS AT HOLMESBURG PRISON* *passim* (1998).

⁷³ *Barrett v. United States*, 798 F.2d 565, 574 (2d Cir. 1986).

⁷⁴ *Hyman v. Jewish Chronic Disease Hosp.*, 248 N.Y.S.2d 245, 247 (1964). See also *Katz on Experimentation*, *supra* note 71, at 9-65.

⁷⁵ *Katz on Experimentation*, *supra* note 71, at 633, 1007-10 (discussing the Willowbrook State School on Staten Island Hepatitis study where retarded children were injected with a strain of hepatitis).

⁷⁶ *Id.*

recommendation from the care provider.⁷⁷ It is unethical for the treating physician to exploit the trust derived from the doctor-patient relationship for the benefit of research. Subjects continue to assume that the suggestion of participation comes from their treating physician. Patients believe their physicians keep their best interest in mind when offering experimental treatments. Thus, the conflict derived from the dual physician/researcher role removes the voluntariness required to obtain the informed consent of a patient-turned-subject.

PART III. ABUSES OF INFORMED CONSENT AND RESPONSES TO THE ABUSES

A. Abuses:

The atrocities committed by the Nazi doctors sentenced during the Nuremberg Trial, in the name of science, served as the modern starting point for the medical ethics dialogue on human experimentation.⁷⁸ During World War II, doctors tortured and mutilated imprisoned individuals, often resulting in death. They submerged concentration camp inmates in freezing water to test how long these individuals could survive. Other subjects suffered mutilation at the hands of surgeons. These people were used merely as means to an end.⁷⁹ The Nazi doctors justified their experimentation with the goal of advancing science. The Nuremberg Code was formulated as a response to the Doctors' Trial.⁸⁰ The code consisted of ten rules, or the ten "commandments" of ethical human research.⁸¹ The code established standards to use in evaluating the study's scientific value and purpose in eight of its rules.⁸² The remaining two rules focused on obtaining informed consent.

In the United States, violations of the Nuremberg Code occurred before, during, and after the Doctors' Trial. The Public Health Service (PHS) ran the infamous Tuskegee Syphilis Study between 1932 and 1972.⁸³ The study took place in rural Macon County, Alabama, a community of poor African-Americans. The study's goal was to observe and to categorize the natural history of syphilis in order to

⁷⁷ P.S. Appelbaum, *False Hopes and Best Data: Consent to Research and the Therapeutic Misconception*, HASTING CENTER REP., April 1987, at 20, 21; Letter from Niels Lynoe, Umea University Sweden to The New England Journal of Medicine, 344 NEW ENG. J. MED. 460, 460 (Feb 8, 2001); Amelia L. Schultz, *Are Research Subjects Really Informed?*, 23 W. J. MED. 76, 78-80 (1975).

⁷⁸ M.A. Grodin & G.J. Annas, *Legacies of Nuremberg: Medical Ethics and Human Rights*, 276 J. AM. MED. ASS'N. 1682 (1996); Jay Katz, *The Consent Principle of the Nuremberg Code: It's Significance Then and Now*, in THE NAZI DOCTORS AND THE NUREMBERG CODE: HUMAN RIGHTS IN HUMAN EXPERIMENTATION 227-239 (G. J. Annas & M.A. Grodin, eds., 1992).

⁷⁹ See "The Medical Case," *Nuremberg Trials Held by the United States of American under Control Council No. 10*, Web Genocide Documentation Centre, http://www.ess.uwe.ac.uk/genocide/cntrl10_trials.htm (last visited Sept. 20, 2006) (discussing United States v. Karl Brandt et. al where German physicians conducted extreme, tortuous medical experiments on non-consenting inmates in concentration camps without consideration of pain and suffering of the subjects).

⁸⁰ See *Nuremberg Code*, *supra* note 5 (defining legitimate medical research, first written in the Doctors' Trial, one of the Nuremberg Trials at the end of World War II conducted in response to human experimentation conducted by the Nazis).

⁸¹ See Shuster, *supra* note 9 (quoting the Nuremberg Code in its entirety).

⁸² See *Nuremberg Code*, *supra* note 5 (establishing a code of ethics for human research in rules 2-8, 10).

⁸³ JAMES H. JONES, *BAD BLOOD: THE TUSKEGEE SYPHILIS EXPERIMENT* 5 (1981).

determine if the disease progressed differently in blacks and whites. The subjects were 399 black men with syphilis, and 201 control subjects. These men were never informed that they were part of a study, and therefore, they never consented to be in the study. In the 1940s, when penicillin became available, these men were not treated. In fact, the PHS went to great lengths to prevent the subjects from obtaining treatment. Although peer reviewed medical literature published parts of the study, there was never an objection from the medical community.⁸⁴ Tuskegee openly violated the absolute requirement of informed consent in the Nuremberg Code. The study had a flawed ethical and scientific basis, which did not satisfy those requirements of the Code. The Tuskegee example made it clear that society cannot rely on those in positions of authority, specifically physicians, to act in the best interest of subjects.⁸⁵

The beneficence of physicians cannot be relied on in the research arena. The Tuskegee physicians/researchers exhibited no respect for the autonomy of their subjects, but rather used their professionalism to exploit subjects. Even after its exposure, some of these physicians continued to defend the study.⁸⁶ These subjects lived in the poor, rural, segregated south, they were obedient to authority, and they were vulnerable. The study was their only access to health care therefore, even if the subjects consented to the study, their consent was not voluntary.⁸⁷

Events from the Jewish Chronic Disease Hospital in Brooklyn demonstrate how physicians/researchers often put research above the best interest of patients.⁸⁸ At this hospital, physicians injected cancer cells into twenty-two elderly and debilitated patients without the patients' knowledge or consent.⁸⁹ The study's goal was to examine how quickly the patients could reject the cancer cells. Physicians performed these injections using an experimental protocol, to advance scientific knowledge, with no intention of treating the patients and the hospital approved the study.⁹⁰

Prisoners are another vulnerable class that has often been subject to experimentation.⁹¹ Consent obtained from prisoners is not voluntary and informed because these individuals are a captive population, eager to earn whatever money possible. The situation of confinement makes it impossible for prisoners to make a decision based on free will. The prisoners might receive special benefits for research participation that can ease their quality of life. They might feel obligated to participate, in which case the experiments erode their ability to exercise autonomy. The Department of Health and Human Services restricted experimentation on

⁸⁴ *Id.*

⁸⁵ PATRICIA KING, RACE JUSTICE AND RESEARCH IN BEYOND CONSENT: SEEKING JUSTICE IN RESEARCH 88-110 (Jeffrey P. Kahn, Anna C. Mastroianni & Jeremy Sugarman, eds.) (1998).

⁸⁶ Allan M. Brandt, *Racism and Research: The Case of the Tuskegee Syphilis Study*, Hasting Ctr. Rep. 8:21-29 (1978).

⁸⁷ JONES, *supra* note 83, at 5.

⁸⁸ See Hyman, *supra* note 74, at 339 (discussing the failure of a physician to disclose information from a research study).

⁸⁹ *Id.*

⁹⁰ *Id.*

⁹¹ HORNBLUM, *supra* note 72 (recounting the questionable experimentations on prisoners that occurred at the Philadelphia Holmesburg Prison from the mid-1940s until 1974).

prisoners in 1978 under guidelines for “Protection Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects.”⁹²

B. Case Law:

The case law pertinent to the violation of informed consent in experimentation consists of relatively few tort cases.⁹³ In *Burton v. Brooklyn Doctors Hospital*,⁹⁴ doctors treated a premature infant a high concentration of oxygen as part of a study to determine if lower concentrations of oxygen than normally given were sufficient to prevent brain damage while preserving the baby’s eyesight. The doctors made no attempt to get informed consent from the baby’s parents. The hospital running the experiment performed prior studies showing that high concentrations of oxygen given to premature infants caused blindness.⁹⁵ The Appellate Division of the New York Supreme Court found that no medical reason existed for giving a child high oxygen, except for the random allocation process required by the study.⁹⁶ The court also found that the physicians improperly failed to inform the parents of the risks,⁹⁷ and held in favor of the plaintiff.⁹⁸

The medical profession argued that investigators guided by ethical concerns and the beneficence of physicians will guide researchers.⁹⁹ Violations of that protection of patients, such as those in *Burton*, are not as rare as one might suppose. In 1966, Henry Beecher, a prominent anesthesiologist from Harvard, published a landmark article in the *New England Journal of Medicine*.¹⁰⁰ In this article, Beecher outlined his concerns about the ethics of medical research.¹⁰¹ He detailed twenty-two studies that violated informed consent, using them as examples of how the push for evidence-based medicine increased ethically wrong behaviors in medical research.¹⁰² Prior to general application of new procedures, researchers experimenting with subjects are required to show the benefit of the new therapies. Beecher expressed concern that newly available sums of money for research, coming from hospitals and the National Institutes of Health, could increase the ethical and informed consent violations in human research.¹⁰³ In discussing the issue of consent, Beecher pointed out that a patient will almost always consent to any request their physician makes.¹⁰⁴ However, most patients will not “agree to jeopardize [their] health or [their] life for

⁹² Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects, 43 Fed. Reg. 53,655 (Nov. 16, 1978).

⁹³ Goldner, *supra* note 47, at 88.

⁹⁴ 452 N.Y.S.2d 875, 877-79 (N.Y. App. Div. 1982).

⁹⁵ *Id.* at 877, 879.

⁹⁶ *Id.* at 879.

⁹⁷ *Id.*

⁹⁸ *Id.* at 882.

⁹⁹ F.J. Inglefinger, *Informed but Uneducated Consent*, 87 NEW ENG. J. MED 465-466 (1972).

¹⁰⁰ Henry K. Beecher, *Ethics and Clinical Research*, 274 NEW ENG. J. MED 1354 (1966) [hereinafter *Beecher on Ethics and Research*].

¹⁰¹ *Id.* at 1354 (including lack of total explanations of risks to patient, lack of knowledge of participation in study, and treatment for the benefit of patients in general rather than the specific patient’s benefit).

¹⁰² *Id.*

¹⁰³ *Id.* at 1355.

¹⁰⁴ *Id.*

the sake of science.”¹⁰⁵ To protect the patient/subject, Beecher suggested investigators always strive for fully informed consent, and clarify that the patient/subject is participating in an experiment. Beecher deemed the second safeguard the more reliable of the two, which would be “the presence of an intelligent, informed, conscientious, compassionate, responsible investigator.”¹⁰⁶

Beecher did well to identify the issues at such an early stage in the race for medical advancement. The funding for medical studies through federal programs, including the National Institutes of Health, increased dramatically since the publication of Beecher’s article. Perhaps of greater concern is the current trend for research funding from private sources, such as medical device manufacturers and pharmaceutical companies, who are funding increasing amounts of research. Privately funded human research trials are often joint ventures with academic institutions or private physicians. This private research leads to increased pressures on physicians/researchers, who now must recruit subjects to fulfill their obligations to outside agencies. The financial stakes are increased as federal funding is becoming harder to obtain. To continue to remain academically productive, physicians/ researchers are driven to join forces with companies, whose goal is to promote a specific product. It is unlikely that the investigator remain independent and unbiased in the face of financial pressures. Even if the physicians/researchers could remain unbiased, treating physicians should never suggest that a patient participate in such a study. They could not fulfill the requirements for obtaining informed consent, even after disclosing their interests fully. Specifically, the physicians’ relationships with their patient would interfere with the patient/subject’s ability to make a free and informed decision.¹⁰⁷ These and other potential problems in informed consent and human experimentation led to federal legislation for regulating scientific investigation.¹⁰⁸ The response to investigators’ breaches of ethics predominantly occurred through the federal legislature.¹⁰⁹

C. Responses:

The response to breaches in medical research ethics began with the Nuremberg Code, which formed the basis for much of the law on human research ethics and regulation.¹¹⁰ Eight of the rules in the Nuremberg Code addressed the ethics of a research project itself, and focused on the scientific validity and safety of the proposed investigation.¹¹¹ These criteria were best determined by scientists who understand the study’s science and the methodology.

The two remaining rules focused on informed consent, and thereby empowered

¹⁰⁵ *Id.* (Beecher qualifies this statement by recognizing that suitable patients will accede on the basis of trust to their physician’s request).

¹⁰⁶ *Beecher on Ethics and Research*, *supra* note 100, at 1360.

¹⁰⁷ Howard M. Spiro, *Constraint and Consent-On Being a Patient and a Subject*, 293 NEW ENG. J. MED 1134 (1975).

¹⁰⁸ R. FADEN AND T. BEAUCHANP, A HISTORY AND THEORY OF INFORMED CONSENT 200 (1986).

¹⁰⁹ Pub. L. No. 93-348 (1974); 45 C.F.R. § 46.

¹¹⁰ *Nuremberg Code*, *supra* note 5.

¹¹¹ *Id.* at Rules 2-8, 10.

the subject by protecting human rights.¹¹² No longer was the research subject at the mercy of the investigator because the researcher had the affirmative duty to make certain that the subject is truly informed.¹¹³ The investigator could not delegate this responsibility with impunity. Rule number one addressed the requirements of informed consent,¹¹⁴ and Rule number nine required that the subject have the right to terminate the experiment.¹¹⁵ For the first time, these rules suggested that the research subject should be empowered with respect to participation in studies, and no longer rely solely on the ethics of researchers. The Nuremberg Code made the requirement of informed consent inviolate. There was no balancing of personal autonomy with the benefit of scientific research to society as a whole, and there were no exceptions to the prerequisite of informed consent. Based on the evidence in the Doctors' Trial, it was clear to the world that society could not rely on the ethics of researchers, particularly physicians, to protect the best interest of human research subjects.¹¹⁶ The authors of the Code gave research subjects the power to consent after full disclosure and to terminate the research at will.

The World Medical Association (WMA) introduced the *Declaration of Helsinki* in 1964.¹¹⁷ In the introduction, the WMA defines the acceptable purposes of human research as the improvement of "diagnostic, therapeutic and prophylactic procedures and the understanding of the etiology and pathogenesis of disease."¹¹⁸ The *Declaration of Helsinki* makes a distinction between therapeutic and non-therapeutic research.¹¹⁹ The requirement of informed consent is explored in Basic Principle #9 of the *Declaration of Helsinki*.¹²⁰ Basic Principle #10 applies specifically when the subject is in a dependent relationship with the investigator. If the *Declaration of Helsinki* is applied, the voluntariness of the patient/subject's consent is lost. In such a situation, the patient's consent is invalid until an independent physician, not engaged in the investigation, obtains the patient's informed consent.¹²¹

Unfortunately, Part II of the *Declaration of Helsinki*, dealing with clinical research, erodes the right of autonomy of the subject in therapeutic research.¹²² In research, the risks and benefits to be gained by experimental treatment are to be

¹¹² *Id.* at Rules 1, 9.

¹¹³ *See id.* (requiring investigator to obtain voluntary informed consent of human subject, and permitting human subject to end research at any time if subject believes that completing the research would be impossible).

¹¹⁴ *Id.* at Rule 1

¹¹⁵ *Id.* at Rule 9.

¹¹⁶ *Nuremberg Case 1*, *supra* note 3; *see also* THE UNITED STATES HOLOCAUST MEMORIAL MUSEUM, THE DOCTORS TRIAL *available at* <http://www.ushmm.org/research/doctors/telford.htm> (last accessed Oct. 20, 2006) (documenting the prosecution's opening statement at the Doctor's Trial).

¹¹⁷ World Med. Ass'n., *Declaration of Helsinki: Recommendations Guiding Physicians in Biomedical Research Involving Human Subjects*, Adopted by 18th World Med. Assembly, Helsinki, Finland, June 1964 [hereinafter *Declaration of Helsinki*].

¹¹⁸ *Id.*

¹¹⁹ *Id.* at Parts II-III.

¹²⁰ *Id.* at Basic Principle #9 (explaining the requirements necessary for informed consent, including awareness of goals of study, benefits/drawbacks of study, and possible personal discomfort, and also awareness of right to withdraw consent at any time).

¹²¹ *Id.* at Basic Principle #10.

¹²² *Id.* at Part II.

weighed against the risks and benefits of applying the standard treatment.¹²³ In other words, every patient should receive the best-proven treatment, even the control group.¹²⁴ In Basic Principle #5, the requirement of obtaining informed consent may be waived entirely if “the physician considers it essential not to obtain informed consent.”¹²⁵ Often referred to as the therapeutic privilege, this concept is usually used in the context of medical treatment. Unfortunately, by permitting the physician to get around consent in research, the Declaration endorses a standard of informed consent that falls below the common law standard for consent to treatment.¹²⁶

Under the common law concept of “therapeutic privilege,” if the treating physician believes, in the specific circumstances of the particular patient, that informing the patient of the risks will be harmful, the physician need not obtain consent.¹²⁷ Under the privilege, the process of obtaining informed consent must cause harm to the patient, not the patient’s refusal to consent. The privilege will not apply when the patient rejects an intervention suggested by the physician.¹²⁸ If the interpretation of therapeutic privilege is that broad, the exception would swallow the rule, and the requirement of informed consent in treatment could always give way to the beneficence of physicians. In research, however, there is no known benefit to withholding informed consent from the subject, and therefore, the concept of therapeutic privilege is not valid. Instead, if the process of obtaining consent may injure the patient, then the subject should not be recruited for research.

The recent October 2000 revision of the *Declaration of Helsinki* removes this exception.¹²⁹ Under the revised *Declaration*, the investigator, in potentially therapeutic experiments, can no longer decide for the subject whether consent is necessary.¹³⁰ The revised *Declaration* further requires that separation of treatment and research should be made clear to the patient, although it describes no method to effectuate this requirement. The current revision also strengthens and clarifies the stance that placebo arms, or control groups receiving no treatment, are not ethical, unless no alternate accepted treatment exists.¹³¹ All patients must receive the best, known treatment and receive full disclosure of all the physician’s relevant financial interests.¹³² In the remainder of the *Declaration of Helsinki*, the WMA delineates the ethics of the research itself.¹³³

To rely solely on the physician / investigator’s beneficence and ethics in research

¹²³ *Declaration of Helsinki*, *supra* note 117, at Part II, Sect. 2.

¹²⁴ *Id.* at Part II, Sect. 3 (this led to a debate in the medical and ethics literature that continues today. Taking this into account there would no longer be any placebo controlled trials).

¹²⁵ *Id.* at Part II, Sect. 5.

¹²⁶ PAUL APPELBAUM ET. AL, INFORMED CONSENT: LEGAL THEORY AND CLINICAL PRACTICE 214-15 (1987).

¹²⁷ *Id.* at 72-73.

¹²⁸ *Id.* at 75-76.

¹²⁹ World Med. Ass’n., *Declaration of Helsinki: Recommendations Guiding Physicians in Biomedical Research Involving Human Subjects*, Adopted by 52nd World Med. Assembly, Edinburgh, Scotland, October 2000, reprinted in 284 J. AM. MED. ASS’N. 3043-45 (2000).

¹³⁰ *Id.* at ¶ 20-26.

¹³¹ *Id.* at ¶ 29.

¹³² *Id.* at ¶ 22.

¹³³ *Declaration of Helsinki*, *supra* note 117, at Part III.

would violate the Nuremberg Code. The distinction between research and treatment fundamentally concerns the unknown. While research involves interventions with unknown outcomes,¹³⁴ the outcomes in medical research, as defined by the *Belmont Report*, are already accepted and known.¹³⁵ Whether the research is therapeutic or purely non-therapeutic, the benefit is unknown. Therefore, the requirement of maintaining a subject's autonomy is fundamental,¹³⁶ and informed consent should be a requirement.

Research, in contrast to treatment, is further described as a rigid protocol for the advancement of knowledge and the potential benefit of society at large. The protocol is not varied based on the individual needs of subjects.¹³⁷ This protocol is in contrast to treatment, where the intervention is tailored to the individual patient's best interest. If the initial action proves unbeneficial for the individual, then the physician reassesses the treatment and changes course. In this manner, the best interest of the patient directs the suggested treatment. For research, particularly protocol-driven research, the individual is treated as part of a larger group. The assignment of subjects to protocols is not directed by the subjects' best interest. The research protocol cannot be altered even if another course might be better. The constraints of research are consequently much more rigid than those of treatment.

This distinction between research and treatment is not always clear.¹³⁸ Nancy King suggests, in *Hastings Center Report*, that this distinction should be dropped and the standard for informed consent should be the same in both categories.¹³⁹ King's solution involves a meaningful discussion between the patient/subject and the physician/investigator.¹⁴⁰ However, her analysis fails to consider the intent-based distinction between research and treatment. In *The Regulation of Human Experimentation in the United States-A Personal Odyssey*, Jay Katz also voices concern that the research-treatment distinction may allow investigators to label interventions as treatment, when they are, in fact, experimental.¹⁴¹

I submit that the difference between research and standard treatment is not difficult in most instances. Medical malpractice is based on the physician's

¹³⁴ *Belmont Report*, *supra* note 8, at 23,193 ("The term 'research' designates an activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships). Research is usually described in formal protocol that sets forth an objective and a set of procedures designed to reach that objective").

¹³⁵ *Id.* ("For the most part, the term "practice" refers to interventions that are designed solely to enhance the well-being of an individual patient or client and that have a reasonable expectation of success. The purpose of medical or behavioral practice is to provide diagnosis, preventive treatment or therapy to particular individuals").

¹³⁶ *Id.* at 23,196.

¹³⁷ See, e.g., Dominique Sprumont, *Resolving the Inherent Dissonance Between the Doctor's Roles as Healer and Researcher: A Proposal*, in RESEARCH ON HUMAN SUBJECTS: ETHICS, LAW AND SOCIAL POLICY 547-554 (David N. Weisstub, ed., 1998); Matthew Miller, *Phase I Cancer Trials: A Collusion of Misunderstanding*, HASTINGS CTR. REP., July-Aug. 2000 at 34, 39-40.

¹³⁸ Nancy M. P. King, *Experimental Treatment Oxymoron or Aspiration?*, HASTINGS CTR. REP., July-Aug. 1995 at 6-15.

¹³⁹ *Id.* at 12-13.

¹⁴⁰ *Id.* at 13.

¹⁴¹ Jay Katz, *The Regulation of Human Experimentation in the United States-A Personal Odyssey*, IRB: REV. HUM. SUBJECTS RES. Jan.-Feb. 1987.

deviation from the standard practice. Juries make this distinction on a regular basis, thus, it would seem plausible that we could make the same differentiation between research and treatment prospectively. Therapeutic experimentation, however, *is* an oxymoron because treatment and experimentation are distinct.¹⁴² Experimental interventions cannot be treatment until they become standard practice, and then, by definition, are no longer experimental.

Physicians who participate in clinical trials run by industry are well aware that these are experiments and not proven therapies; that is the reason for the study. The exception to the rule is the study physician acting alone, who tries a novel treatment for a particular ailment with no other intentions but to cure the patient. The ethical guidelines of the American Medical Association (AMA) stipulate that research on human subjects must be organized and protocol driven, so that valid scientific results can be obtained.¹⁴³ Novel treatments by individual physicians would fail this test. These new treatments are not research; furthermore, the ethics and legal standing of a particular novel treatment depends on the particular treatment's acceptance in the medical community, and the adequacy of informed consent. Unfortunately, the implementation of novel treatments without further research may lead to ineffective treatments becoming accepted practice. The later sections of this paper will discuss the importance of the physician/researcher's intent and its relationship to the inviolate nature of informed consent in research.

D. Federal Regulation:

The government produced little regulation on research ethics until 1962.¹⁴⁴ Until this time, the responsibility for the regulation of research and ethics rested on research institutions and investigators. This standard was analogous to the professional standard of disclosure, in informed consent for treatment, prevalent at that time.¹⁴⁵ The beneficence of physicians was assumed to carry over into the realm of research. Society continued to rely on the professionalism of physicians to protect the autonomy, health, and well-being of the individual subjects of human research. The multiple infamous transgressions of individual autonomy in the name of research had yet to move the federal government to action. Interestingly, beginning in the 1940s, the Department of Defense and the Atomic Energy Commission devoted time and effort to discussing the ethics of experimentation.¹⁴⁶ The Armed Forces Medical Policy Council, in 1952, adopted ethical principles from the Nuremberg Code as guidelines for research into atomic, biologic, and chemical warfare.¹⁴⁷

¹⁴² *Belmont Report*, *supra* note 8, at 23,193.

¹⁴³ AM. MED. ASS'N. CODE OF ETHICS E-207 (1998), <http://www.ama-assn.org/ama/pub/category/8422.html> (last visited Sept. 21, 2006).

¹⁴⁴ *See generally* DENNIS M. MALONEY, PROTECTION OF HUMAN RESEARCH SUBJECTS: A PRACTICAL GUIDE TO FEDERAL LAWS AND REGULATIONS (1984).

¹⁴⁵ McClellan, *supra* note 40, at 82-83.

¹⁴⁶ *See* ADVISORY COMM. ON HUMAN RADIATION EXPERIMENTS, FINAL REPORT OF THE ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENT 8-9 (1996). [hereinafter ACHRE]. *See generally* Morin, *supra* note 71, at 169.

¹⁴⁷ ACHRE, *supra* note 146, at 57.

The debate over regulation of research grew as the press disclosed blatant violations of research ethics to the public. The first step in regulating research was in 1953 with the opening of the National Institutes of Health's (NIH) Clinical Center.¹⁴⁸ The NIH set up loose guidelines for subject consent, but these rules only applied to research performed in the Clinical Center and not to outside research funded by NIH.¹⁴⁹ The restrictions were very limited, and applied solely to research with an unusual hazard.¹⁵⁰ The consent requirement only applied to volunteer subjects, who had no possibility of benefiting from the research.¹⁵¹ Therefore, the regulations did not apply to patients. In 1962, the FDA began regulating clinical drug investigations, requiring proof of therapeutic efficacy in addition to the safety of the study.¹⁵² The FDA relied upon the constitutional power of the Commerce Clause to regulate all such investigations, regardless of the funding source. The FDA's regulations applied to new drugs and to investigational devices.¹⁵³

In 1966, the NIH, under the Public Health Service, issued a statement requiring prospective review of all proposed research funded by the Department of Health Education and Welfare.¹⁵⁴ Congress codified these rules into federal regulations, with the most recent significant revision in 2005.¹⁵⁵ These regulations, often referred to as the "Common Rule," required institutional review boards to prospectively evaluate proposed human research. The role of these institutional review boards (IRBs) is to decentralize the control of research project oversight. Idealistically, IRBs exist to protect the subject's rights and autonomy. Practically, IRBs' members are primarily from the institution performing the research. The regulatory requirement is that IRBs have, at minimum, five members but only one member must be from outside the parent institution.¹⁵⁶

The federal regulations applied only to research funded, or specifically regulated, by federal agencies.¹⁵⁷ This restriction contradicted the FDA regulatory scheme, which applied more broadly, but applied only to investigational drugs and devices.¹⁵⁸ In all other respects, the rules applied by the FDA are essentially the same as those applied to federally funded research. The section of the federal regulations on informed consent does not define this term nor does it delineate the process of

¹⁴⁸ APPELBAUM ET. AL, *supra* note 126, at 215-16 (citing M.S. Frankel, *The Development of Policy Guidelines Governing Human Experimentation in the United States: A Case Study of Public Policy-Making for Science and Technology*, 2 ETHICS SCI. MED. 43-59 (1975)). See generally DENNIS M. MALONEY, PROTECTION OF HUMAN RESEARCH SUBJECTS: A PRACTICAL GUIDE TO FEDERAL LAWS AND REGULATIONS (1984) (giving an excellent history of the evolution of legislation of research ethics).

¹⁴⁹ William J. Curran, *Governmental Regulation of the Use of Human Subjects in Medical Research: the Approach of Two Federal Agencies*, in EXPERIMENTATION WITH HUMAN SUBJECTS 409, 412 (Paul A. Freund ed., 1970).

¹⁵⁰ *Id.*

¹⁵¹ APPELBAUM ET. AL, *supra* note 126, at 216.

¹⁵² *Id.* at 216-17. See also 108 CONG. REC. 1, 395-99 (1962) (Senate debate of the Drug Industry Act of 1962).

¹⁵³ APPELBAUM ET. AL, *supra* note 126, at 217.

¹⁵⁴ *Id.*

¹⁵⁵ Basic HHS Policy for Protection of Human Research Subjects, 45 C.F.R. § 46.101 (2005).

¹⁵⁶ IRB Membership, 45 C.F.R. § 46.107.

¹⁵⁷ *Id.*

¹⁵⁸ 21 C.F.R. § 50.1 (2001).

obtaining consent.¹⁵⁹ Instead, the federal regulation lists eight general elements of informed consent¹⁶⁰ and outlines a method of documentation for it once obtained.¹⁶¹

Section 46.117 also lists exceptions to the requirement of informed consent.¹⁶² Under this section, the requirements of informed consent may be waived if certain requirements are met, including if the research poses only minimal risk.¹⁶³ The potential subjects do not decide if the risk is minimal, the decision is made for them. In fact, subjects never have the opportunity to evaluate the risk's magnitude in deciding whether or not to participate in experimentation.¹⁶⁴ This fact usurps the autonomy of the subjects, thereby violating the absolute requirement of informed consent in the Nuremberg Code.¹⁶⁵ The exceptions to the requirement of informed consent in the Common Rule are set forth in 45 C.F.R. § 46.116, part d, and are as follows:

- (1) The research involves no more than minimal risk to the subjects;
- (2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- (3) The research could not practicably be carried out without the waiver or alteration; and
- (4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.¹⁶⁶

These exceptions erode the protections of the Nuremberg Code. These exceptions put the decision of what information to disclose in the hands of the investigators or the reviewing IRBs. These rules subsume the individual's free choice in the name of science.

The members of the IRB are almost all members of the institution applying for federal funding. Thus, do the regulations put "Dracula in charge of the blood bank"?¹⁶⁷ This utilitarian approach to the advancement of science and medical treatment restricts the fundamental rights of bodily integrity and autonomy. Such balancing of benefits does not occur unless the opposing interest is a compelling state interest.¹⁶⁸ The advancement of science and the acquisition of knowledge are

¹⁵⁹ General Requirements for Informed Consent, 45 C.F.R. § 46.116.

¹⁶⁰ *Id.*

¹⁶¹ 45 C.F.R. § 46.117.

¹⁶² 45 C.F.R. § 46.116(d) (explaining that the process of obtaining informed consent is waived if, for example, there is only minimal risk to the subject or if the particular research protocol does not involve a procedure that normally requires written consent).

¹⁶³ *Id.*; see also 45 C.F.R. § 46.117 (c)(2) (explaining that the process of obtaining informed consent is waived if, for example, there is only minimal risk to the subject or if the particular research protocol does not involve a procedure that normally requires written consent).

¹⁶⁴ See *id.* (outlining the direct consequences of waiver of the elements of informed consent).

¹⁶⁵ *Nuremberg Code*, *supra* note 5, at Rule 1.

¹⁶⁶ 45 C.F.R. § 46.116(d).

¹⁶⁷ Paul M. McNeill, *International Trends in Research Regulation: Science as Negotiation*, in RESEARCH ON HUMAN SUBJECTS: ETHICS, LAW AND SOCIAL POLICY 243, 245 (David N. Weisstub ed., 1998) (illuminating the problem that colleagues who come from the same institution will have the same biases towards their research that is being scrutinized, in effect putting the research in as much danger as a blood bank would be if Dracula were to be in charge of monitoring it).

¹⁶⁸ See J. S. MILL, ON LIBERTY 267 (London, Benton 1859) (stating that in order to protect individual autonomy, power may only be exerted over an individual if that exertion is necessary to protect *others*).

not compelling state interests because they do not remediate immediate harms.¹⁶⁹ To balance all possible benefits to society against the rights of individuals, exceptions can always be found for obtaining informed consent. The advancement of science does not override individual autonomy; therefore, there should be no balancing of a societal benefit against the risk to the individual.¹⁷⁰

The federal regulation serves to protect the institutions conducting the research, perhaps even more so than the subjects. The IRBs are not required to supervise consent, nor are there any guidelines for the process of obtaining consent.¹⁷¹ The regulation is very vague in its description of informed consent.¹⁷² The circumstances of obtaining informed consent are required to give the subject sufficient opportunity to consider whether or not to assent, and to minimize the possibility of coercion and undue influence.¹⁷³ The regulation provides no clarification of what this process entails, nor are there guidelines for IRBs in evaluating compliance.¹⁷⁴ The requirement of understanding for informed consent is not adequately addressed in the current federal regulation.¹⁷⁵ The concept of voluntariness required for informed consent is given even less consideration in the Common Rule.¹⁷⁶ Only the very general guidelines given above address that consent must be voluntary.¹⁷⁷

The current system of insuring the protection of research subjects is inadequate. IRBs play only a cursory role in reviewing studies. The definition of minimal risk is vague and relies on the IRB's definition, and not on national reviews or standards.¹⁷⁸ The IRBs' role in reviewing the scientific value of the study perhaps is adequate, but that will not be discussed in this paper. The ability of an IRB to sufficiently protect the patient's autonomy does not exist in the current system. A recent study shows that some IRBs only spend one or two minutes reviewing each study.¹⁷⁹ Most IRBs

from harm).

¹⁶⁹ *Id.*

¹⁷⁰ *Id.* at 267 (likely agreeing that the requirement of informed consent is not a pressing societal harm because the pursuit of freedom by the individual does not restrict any other individual's same right).

¹⁷¹ *But see* 45 C.F.R. § 46.116(a) (delineating the basic elements that must be included in an informed consent and implying that informed consent may be provided orally or in written form).

¹⁷² *See generally* 45 C.F.R. § 46.116(a) (laying out the four basic elements that are required to be included when informed consent is given).

¹⁷³ *See* 45 C.F.R. § 46.116(a) (detailing the general requirements of informed consent, which convey such pertinent information as the foreseeable risks of the research, explanation of the purposes, advantageous alternative procedures for the subject, and the ability to voluntarily quit the study at any time without penalty or loss of benefit).

¹⁷⁴ *Id.*

¹⁷⁵ *Id.*

¹⁷⁶ *See* 45 C.F.R. § 46.116 (stating that participation is "voluntary" without including any specific definition of the concept).

¹⁷⁷ *Id.*

¹⁷⁸ Federal regulations define minimal risk as a risk for which "the probability and magnitude of harm or discomfort anticipated . . . are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. 45 § C.F.R. § 46.102(i). However, there is disagreement as to how to apply this definition of minimal risk, resulting in self-determinations by IRBs of what constitutes "minimal risk" in a research study. *See* Beverly Woodward, *Challenges to Human Subject Protections in U.S. Medical Research*, 282(20) J. AM. MED. ASS'N. 1947-52, 1949-50 (1999).

¹⁷⁹ G. Grob, *Scientific Research: Continued Vigilance Critical to Protecting Human Subjects*, Washington DC: General Accounting Office; GAO/HEHS-96-72 (1996) (stating that most IRBs have

in the U.S. consist primarily of scientists; therefore, the reviewing institutional body is similarly situated to the scientists/physicians who plan to conduct the study. The process of review can thus be equated to the early common law of informed consent in treatment. The early rule was the physician (professional) rule of disclosure, based on what the reasonable physician would disclose to their patient.¹⁸⁰ As outlined above, the reasonable patient standard now replaces the professional standard with regard to disclosure.¹⁸¹

The courts applied and ethicists suggested an analogous standard to use in research, or the reasonable subject standard of disclosure. This rule is not followed with IRBs. In other countries IRBs, or their equivalent, are made up of a much larger percentage of community members. For example, in the Dutch system, half of the IRB consists of non-scientist community members.¹⁸² Australia has a similar system, requiring a broader representation of laypersons on their review boards than in the U.S.¹⁸³ The Department of Health and Human Services, Office of Inspector General suggested a large percentage of the IRBs should consist of laypersons from the community.¹⁸⁴ The larger number of community members makes the board better able to assess what information the “reasonable subject” would require in order to make an informed decision regarding whether to participate in a study or not.¹⁸⁵ The criticism of these community IRBs is that the members cannot understand the science or the value of the research. This criticism, in a nutshell, exemplifies the problem with the current system and the prevalent attitude in the scientific community. If the potential subject cannot at some level understand the science, as well as the risks and benefits of the study, voluntary informed consent would be impossible to obtain. However, the subject’s understanding should not be viewed as an obstacle to scientific and medical progress, but as an integral part of human subject research. Understanding is necessary to maintain individual autonomy and the integrity of the medical and scientific communities.

The criticism that the lay public may accept scientific studies with unacceptable scientific validity would make community review boards (CRBs) inadequate. That criticism presents a very different argument from an assertion that CRBs cannot understand the science enough to evaluate the adequacy of disclosure. By setting up a dual review system, the government would solve the valid concern that unacceptable science may pass by the CRBs. The first review would be by a scientific review board, not unlike our current IRBs. They would evaluate the merit of the study on scientific grounds. If the study passed this first review, only then

such a significant number of studies to review for approval that one to two minutes is the maximum time they can allot to reviewing a particular research proposal).

¹⁸⁰ *Schloendorff*, *supra* note 39, at 134-35.

¹⁸¹ *Canterbury*, *supra* note 43, at 786-87 (standard requiring the disclosure of all information material to the reasonable patient’s decision).

¹⁸² Andre Menache, *Healthy Human Volunteers and Informed Consent*, 19 MED. LAW 523, 525 (2000) (citing the Danish Central Sci. Ethical Comm.; UN Collection of Annexes, Copenhagen (1994)).

¹⁸³ Roy Beran, *The Ethics of Clinical Research and the Conduct of Clinical Drug Trials: International Comparisons and Codes of Conduct*, 19 MED. LAW 502, 516 (2000).

¹⁸⁴ Department of Health and Human Services; Office of Inspector General, *Inst. Review Bd.: A Time for Reform*, OEI-01-97-00193 (1998).

¹⁸⁵ *Id.*

would it go on to review by the CRB consisting of primarily laypersons. To be valid, the laypersons should be the same make-up as the potential subjects of the experiment. The layperson CRB would determine the adequacy of disclosure and the process of consent.

Unfortunately, the increased funding available from governmental and private sources makes it more difficult for IRBs to adequately evaluate studies.¹⁸⁶ IRBs are over burdened, and their current membership is inadequate to represent the interests of patients.¹⁸⁷ Changes in the membership of the boards, and the addition of supervision of the process of informed consent should be instituted.

In 1995, President Clinton created the National Bioethics Advisory Commission, which released a draft report in December of 2000.¹⁸⁸ The report detailed inadequacies in the federal oversight of human subject research and recommended major changes.¹⁸⁹ At publication, the current administration of President George W. Bush and Congress has not yet acted on this report. The recommended changes included (among others):

1. Congress should create an independent office to oversee human research. Currently the Office for Human Research Protection (OHRP) is under the Department of Health and Human Services.
2. At minimum half of the members of IRBs must be from outside the institution. At minimum half are to be non-scientists.
3. All research should be covered, not only federally funded research.
4. University review boards should supervise the informed consent process under certain situations.¹⁹⁰

In the National Bioethics Advisory Commission's (NBAC) draft policy they extensively outlined the history and reasoning for revamping the current federal scheme of research regulation.¹⁹¹ However, the piecemeal current system is failing in many respects.

Much of the newly proposed regulation is based on the principles set forth in the *Belmont Report*.¹⁹² The National Research Act of 1974,¹⁹³ established the National

¹⁸⁶ *Id.*

¹⁸⁷ See Woodward, *supra* note 178, at 1951(citing G. J. ANNAS, *Good as Gold*, in JUDGING MEDICINE 325 (1988) (describing this negative trend for IRBs as having broader implications on the field of medical care)).

¹⁸⁸ NAT'L BIOETHICS ADVISORY COMM'N, POLICY ISSUES IN RESEARCH INVOLVING HUMAN PARTICIPANTS, (August 2001) (stating in its charter that the Commission "shall direct its attention to consideration of protection of the rights and welfare of human research subjects").

¹⁸⁹ *Id.* at 2-6, 16.

¹⁹⁰ *Id.* at 16; see also Jeffrey Brainard, *Panel Proposes New Guidelines for Research With Human Subjects*, THE CHRONICLE OF HIGHER EDUCATION, January 12, 2001, at A24 (listing the recommendations of the National Bioethics Advisory Commission, which are stated to be somewhat "controversial" because it is difficult to have IRBs composed of laypersons).

¹⁹¹ NAT'L BIOETHICS ADVISORY COMM'N, POLICY ISSUES IN RESEARCH INVOLVING HUMAN PARTICIPANTS, *supra* note 188, at 16.

¹⁹² *Belmont Report*, *supra* note 8, at 23,192 (describing the basic ethical principles of respect for persons, beneficence, and justice that underlie the need for informed consent).

¹⁹³ National Research Act of 1974, Pub. L. No. 93-348 (codified as amended at 42 U.S.C. § 242(a)).

Commission for the Protection of Human Subjects of Biomedical and Behavior Research (National Commission). The National Commission presented the *Belmont Report* to Congress in 1978 and published it in 1979.¹⁹⁴ The major thrust of this report identified three basic ethical principles and applied these principles to research. These rules are: 1) respect for persons, 2) beneficence, and 3) justice.¹⁹⁵ Respect for persons is the underlying ethical principle behind informed consent. Beneficence is translated into a risk versus benefit analysis for the subject. Justice was initially only applied to the selection of participants.¹⁹⁶ A broader use of justice in experimentation now applies to those who will benefit from the research project, in relation to those who take the risk. This balance is particularly relevant in international studies, where the drug studied may not be available to the population who participates in the investigation. The principles in the *Belmont Report* are basic ethical principles. If implemented, they empower the individual without having autonomy and self-determination usurped, and the regulatory scheme will fall in line with the Nuremberg Code. The draft policy of NBAC awaits action by Congress and the President. The proposed regulations are a step in the right direction, but they will not protect the autonomy of subjects whose treating physicians assume the dual role of investigator because these proposals do not address the voluntariness of assent.

The importance of rigid regulation, oversight, and protection of human research subjects becomes increasingly urgent. Current experiments that violate human rights spurred most of this regulation, but violations continue to be uncovered even in the most prestigious universities. An increase in research funding leads to an increased number of research subjects. In 1986, federal funding for medical and health related research was \$6.9 billion.¹⁹⁷ This figure nearly doubled to \$13.4 billion by 1995, and nearly doubled again to \$25.7 billion in 2001.¹⁹⁸ Only approximately half of that funding went to university research programs.¹⁹⁹ An even more threatening change is the increasing privatization of research funding, which is growing at an even faster rate.²⁰⁰ During the same period from 1986 to 1995, private research funding tripled from \$6.2 billion to \$18.6 billion.²⁰¹

Pharmaceutical company research exploded in the past 20 years. In 1980, pharmaceutical companies funded \$1.5 billion in research. By the year 2000, pharmaceutical companies spent \$22.4 billion on human research,²⁰² and more than

¹⁹⁴ MALONEY, *supra* note 148, at 20 (stating that the actual report was based on meetings held in 1976 and consequently, federal actions were implemented to protect research subjects three years before the Belmont Report was officially published in 1979).

¹⁹⁵ *Belmont Report*, *supra* note 8, at 23,192.

¹⁹⁶ *Id.* at Part B (3).

¹⁹⁷ Nat'l Inst. of Health, Award Trends, <http://grants1.nih.gov/grants/award/awardtr.htm#l> (last visited Sept. 20, 2006) (providing an overview of NIH grants, cooperative agreements and contracts to universities, hospitals, and other institutions).

¹⁹⁸ *Id.*

¹⁹⁹ NAT'L BIOETHICS ADVISORY COMM'N, *supra* note 188, at ch. 1, page 4.

²⁰⁰ *Id.*

²⁰¹ *Id.*

²⁰² Pharmaceutical Research and Manufacturers of America, <http://www.phrma.org> (last visited Sept. 20, 2006) [hereinafter *PhRMA*].

\$49.3 billion in 2004.²⁰³ Biotechnology and medical device company funded research also exploded in recent years.²⁰⁴ These companies' roles on the research front became a formidable power.

The current regulation of research funded by industry only applies to drugs and investigational devices that are not yet approved.²⁰⁵ Under the current system, once approved, privately funded research with drugs and devices are no longer under the auspices of the FDA regulatory scheme.²⁰⁶ Further research projects would not be regulated, subject to the Common Rule or IRB review, unless the research is federally funded.²⁰⁷

The dramatic increase in the amount of money available for research greatly increased the number of investigators in the U.S. The total number of investigators regulated by the FDA rose from 5,500 in 1990 to 25,000 in 1996.²⁰⁸ There are estimated to be a total of 50,000 investigators in the U.S. as of 2000.²⁰⁹ These increasing numbers makes the issue of regulation an imposing problem. History disproves the assumption that individual investigators, or their sponsoring institutions, will ensure compliance with research ethics. Systematic regulation and constraints are necessary, but individual potential subjects must remain empowered to make a free and informed choice regarding participation.

The face of health care changed dramatically in the last decade. Managed Care Organizations and competition for patients limited the availability of clinical funding for research.²¹⁰ In response, academic institutions joined forces with industry in research endeavors.²¹¹ These joint ventures led to a set of conflicts of interest that had not previously been addressed by their review boards or on an institutional basis.

Industry sponsored research is not limited to academic institutions. In a CENTER WATCH REPORT, L. Henderson noted that only 40% of industry-sponsored research funding for clinical trials went to academic medical centers in 1994, whereas²¹² 80%

²⁰³ *PhRMA*, Industry Profile 2005, at http://www.phrma.org/2005_industry_profile/ (last visited Sept. 20, 2006).

²⁰⁴ See H. Moses III, *Financial Anatomy of Biomedical Research*, 294 J. AM. MED. ASS'N. 1333, 1335 (2005) (noting that biotechnology and medical device company funding recognized a 102% increase between 1994 and 2003).

²⁰⁵ *FDA Regulations*, *supra* note 28, at §§ 50, 56.

²⁰⁶ *Id.*

²⁰⁷ See generally R.A. Rettig, *The Industrialization of Clinical Research*, 19(2) HEALTH AFFAIRS 129, 130 (discussing the "recent controversies over the protection of human subjects, payment of physicians for recruiting patients to clinical trials, Food and Drug Administration (FDA) removal of approved drugs from the market, and reporting of results of clinical trials [which] have highlighted important facets of clinical research").

²⁰⁸ L. Valigra, *Rooting Out Rogue Investigators*, 4(7) CENTERWATCH 1,5 (1997).

²⁰⁹ NAT'L BIOETHICS ADVISORY COMM'N, *supra* note 188 (citing *Turbulence and Transition: The Top Stories of 1999*, 7(1) CENTERWATCH 1, 5-10 (2000)).

²¹⁰ See Robert E. Mechanic & Allen Dobson, *The Impact of Managed Care on Clinical Research: A Preliminary Investigation*, 15 HEALTH AFFAIRS 72, 85 (1996) (explaining the competitive market created when managed care organizations negotiate reduced prices and direct patients to low-cost care sites).

²¹¹ See generally John I. Gallin & Helen L. Smits, *Managing the Interface Between Medical Schools Hospitals, and Clinical Research*, 277 J. AM. MED. ASS'N. 651, 652 (1997) (discussing academic programs' efforts in trying to find adequate funding for clinical programs).

²¹² L. Henderson, *Centralized AMCs Growing Steadily*, 6(2) CENTERWATCH 4, 5 (1999).

went to academic medical centers in 1991.²¹³ Private organizations managed the remainder of the industry-funded research.²¹⁴ This trend spawned a new type of business, named Contract Research Organizations (CROs). CROs are private companies that manage research projects, instead of leaving their management to academic institutions.²¹⁵ Another model of private research management is Site Management Organizations (SMOs),²¹⁶ which use physician networks and dedicated facilities to manage research. Private physician practices are also sites for industry sponsored research and subject recruitment.²¹⁷ From these examples, it is obvious that the old research model of investigations primarily sponsored by the federal government and performed at academic institutions changed.

The current system is likened to physicians acting as bounty hunters.²¹⁸ Recruitment of subjects for industry sponsored research projects is a lucrative endeavor for physicians. Some pharmaceutical companies reimburse on a per capita basis for the recruitment of subjects.²¹⁹ This financial reimbursement introduces another potential conflict of interest into the physician-patient relationship. Treatment, solely in the patient's best interest, is vulnerable to compromise as a result of the financial interest of the physician/investigator in recruiting subjects. In the wake of decreasing reimbursement and tighter controls on physician practices and income, recruiting subjects is an enticing sideline activity. This change in the milieu of medical practice and the funding and performance of human research brings urgency to the need to overhaul the current system of research regulation. Patients must be protected from the research and related financial interests of their treating physicians.

History makes it clear that we cannot rely on physicians/investigators to self-monitor and regulate research activities. The Tuskegee Study, recent AIDS studies in Africa,²²⁰ the Brooklyn Chronic Disease Hospital case, and the Willowbrook State School Study,²²¹ all lead to that conclusion. Many more indiscretions exist in the name of science. The bounds of research ethics are both an issue for society at large and the individual. Autonomy and self-determination must take precedence over the

²¹³ *Id.*

²¹⁴ *Id.*

²¹⁵ Ass'n of Clinical Research Professionals, *White Paper on Future Trends: Time to Market*, <http://www.acrpnet.org> (last visited Sept. 21, 2006).

²¹⁶ *Id.*

²¹⁷ *Id.*

²¹⁸ See HAROLD VANDERPOOL, *Conflicts of Interest, Introduction to Part II*, in THE ETHICS OF RESEARCH INVOLVING HUMAN SUBJECTS: FACING THE 21ST CENTURY 147, 148 (1996) (discussing financial motivations for recruiting and securing research subjects).

²¹⁹ Jammi N. Rao & L.J. Sant Cassia, *Ethics of Undisclosed Payments to Doctors Recruiting Patients in Clinical Trials*, 325 BRIT. MED. J. 36, 37 (July 2002) (questioning the ethics behind offering doctors monetary benefits to recruit patients for clinical trials).

²²⁰ See generally Thomas C. Quinn, *Viral Load and Heterosexual Transmission of Human Immunodeficiency Virus Type 1*, 342 NEW ENG. J. MED. 921 (2000) (reporting on an AIDS study in Uganda in which hundreds of HIV-positive patients were observed by doctors for over thirty months, but not treated); see also Marcia Angell, *Investigator's Responsibilities for Human Subjects in Developing Countries*, 342 NEW ENG. J. MED. 967 (2000) (referring to the Uganda study in discussing investigators' responsibilities to human research subjects).

²²¹ *Katz on Experimentation*, *supra* note 71, at 633, 1007-10 (discussing the Willowbrook State School on Staten Island Hepatitis study).

advancement of science.

PART IV: DEFICITS IN THE CURRENT REGULATORY SCHEME

The current system of regulation was made in response to specific episodes of patient's rights violations. Regulation varies by federal institution and is not applied to all research.²²² The NBAC draft policy refers to the current scheme as "cobbled."²²³ The proposed changes to federal oversight of human subject research are a step in the right direction. Unfortunately, they only address some of the ethical violations in current medical and health care research. The majority of the regulations and proposed changes are aimed at the ethics of the research project itself and the understanding component of informed consent. The IRBs would be revamped under the proposal, which would help determine what projects were acceptable to society at large (or were even better to the proposed population of subjects). Scientific review for validity and value of the project would presumably continue. A new, independent federal office would oversee and enforce these new rules. Potential review of the process of informed consent would be helpful to insure disclosure and perhaps understanding by the subjects. The change in makeup of the IRBs membership would help insure this as well.

The federal regulations were revised on June 23, 2005, with unfortunately no significant change in the membership requirements for IRBs or in the requirements for informed consent.²²⁴ There were no substantive changes in the rules, including no change in the required elements of informed consent or in the method by which it is obtained. IRBs remain composed primarily of members of the parent institution with no change in the required spectrum of membership.

The current regulations, and those proposed by NBAC, only address the requirement that informed consent be voluntary, with respect to vulnerable populations. There is no discussion, nor are there any regulations, to insure that subjects in general are truly volunteers. Voluntary assent to participation is essential to informed consent. The issue of voluntariness comes to the surface when the treating physician is also the investigator. The patient-physician relationship impedes the ability of the patient to make a free choice.

Patients with illnesses are eager for treatment. Desperate hopes are easily manipulated. Patients trust in their physicians to act in their best interest. The suggestion of participation in a research project is often viewed as a recommendation for treatment.²²⁵ This conviction of benefit is not warranted. This distinction between treatment and research is hardest to make for those with the poorest prognosis. Every effort must be made to dispel this therapeutic misconception if we are to take informed consent seriously. The patient's belief in the beneficence of

²²² See *FDA Regulations*, *supra* note 28 and accompanying text; *Common Rule*, *supra* note 27 and accompanying text.

²²³ NAT'L BIOETHICS ADVISORY COMM'N, *supra* note 188, at 9 (noting that the current system of protection is less effective than it should be in protecting patients and promoting research).

²²⁴ 45 C.F.R. § 46 (2005).

²²⁵ See *Beecher on Ethics and Research*, *supra* note 100, at 1355 (positing that it is a simple matter for a trusted physician to gain consent for any number of things based on their trusted relationship with the patient).

their physician is the basis of the relationship. The belief that the doctor acts in their best interest cannot be removed merely by declaring that ‘this is an experiment and not treatment’.

The doctor-patient relationship can be viewed as a fiduciary relationship.²²⁶ The requirement of fidelity, candor and competence must be met or the duty of the doctor is violated. The tension between the roles of treating physician and investigator breaches the duty of fidelity. No longer is the patient’s best interest the sole concern or motivation for the physician/investigator’s recommended course of treatment or diagnostic scheme for the patient. This conflict of interest on the part of the physician cannot be obviated by disclosure. Candor will not fulfill the duty of fidelity. The tension between the interests of the investigator and the best interests of the patient (also presumably the physician’s interests) are too great to be compartmentalized. The risk of infringing on the patient’s autonomy and right to security of person are too great to leave to chance.

The Model Rules of Professional Conduct of Lawyers (MRPC) is another guide that may be helpful to apply to physicians/investigators.²²⁷ These rules can apply, with some modification, to the ethical conduct required of physicians. For example, MRPC 1.7 might be applicable to the case of informed consent obtained by treating physicians who assume the dual role of investigators.²²⁸ The physician’s duty is to act in the best interest of patients at all times, but the research interest brings interests adverse to the patient. The nature of the physician-patient relationship creates a conflict of interest in which the patient/subject cannot voluntarily consent, even if the physician offers full disclosure and the patient fully understands. MRPC 1.7 deals with the same issue regarding lawyers.²²⁹ Conflicts of interest between the lawyer and the client must overcome four hurdles before they are acceptable as delineated by MRPC 1.7 (b).²³⁰

²²⁶ ARTHUR LAFRANCE, *BIOETHICS: HEALTH CARE, HUMAN RIGHTS, AND THE LAW*, 483, 483 (1999).

²²⁷ AM. BAR ASS’N, *MODEL RULES PROF’L CONDUCT* (2006), available at http://www.abanet.org/cpr/mrpc/mrpe_toc.html (last visited Sept. 21, 2006).

²²⁸ *Id.* Rule 1.7 applies in the case of informed consent obtained by treating physicians, who assume the additional role of investigator.

“Rule 1.7 Conflict of Interest: Current Clients

(a) Except as provided in paragraph (b), a lawyer shall not represent a client if the representation involves a concurrent conflict of interest. A concurrent conflict of interest exists if:

(1) the representation of one client will be directly adverse to another client; or
(2) there is a significant risk that the representation of one or more clients will be materially limited by the lawyer’s responsibilities to another client, a former client or a third person or by a personal interest of the lawyer.

(b) Notwithstanding the existence of a concurrent conflict of interest under paragraph (a), a lawyer may represent a client if:

(1) the lawyer reasonably believes that the lawyer will be able to provide competent and diligent representation to each affected client;
(2) the representation is not prohibited by law;
(3) the representation does not involve the assertion of a claim by one client against another client represented by the lawyer in the same litigation or other proceeding before a tribunal; and
(4) each affected client gives informed consent, confirmed in writing.”

²²⁹ *Id.*

²³⁰ *Id.* at 1.7(b)

The first requirement for an exception is that the lawyer must reasonably believe that the conflict will not adversely affect the client's interest.²³¹ The MRPC indicates that when lawyers have a conflict of interest with their clients, they must obtain informed consent if the conflict is "waivable."²³² This conflict strains and may breach the fiduciary duty of a lawyer to their client, specifically the duty of loyalty (fidelity).²³³ If the conflict is material, and if it is reasonable to believe the conflict will have an adverse affect on the client, then the conflict cannot be waived. Without a reasonable belief by the lawyer that there will be no adverse affect to the client, then clients cannot consent to continued representation by their lawyers.²³⁴ For treating physicians who assume the dual role of physicians/researchers, it will always be unreasonable to assume that a conflict will not adversely affect the patient's interest. The general advancement of knowledge and other interest of the investigator are inherently adverse to the patient's interests to be cured and to get the best medical care possible. Meanwhile, patients make the assumption that their doctor is also acting in their best interest to cure them.

MRPC Rule 1.8(a) prohibits lawyers from having pecuniary interests adverse to their clients, unless the following three requirements are met:²³⁵

- 1.the transaction and terms on which the lawyer acquires the interest are fair and reasonable to the client and are fully disclosed and transmitted in writing in a manner that can be reasonably understood by the client;
- 2.the client is advised in writing of the desirability of seeking and is given are reasonable opportunity to seek the advice of independent legal counsel on the transaction; and
- 3.the client gives informed consent, in a writing signed by the client, to the essential terms of the transaction and the lawyer's role in the transaction, including whether the lawyer is representing the client in the transaction.²³⁶

For lawyers with adverse pecuniary interests to continue to represent clients requires meeting these stringent rules. In medicine, even if pressed, I do not think we can meet these requirements where doctors have pecuniary interests adverse to their patients.

Another analogy to the MRPC is that lawyers can only restrict relationships with clients if done so expressly.²³⁷ This decision is not solely the lawyers'. In the physician-patient relationship, it is the patient's perspective that counts. The doctor-patient relationship exists when the patient believes it does, unless the physician

²³¹ *Id.* at 1.7(b)(1).

²³² *Id.* at 1.7(b)(4).

²³³ *Id.* at 1.7 cmt. 6.

²³⁴ *See Id.* at 1.7 (failing the 4-part test permitting representation, the lawyer may not continue to represent a client in the presence of a conflict of interest).

²³⁵ *Id.* at Rule 1.8(a).

²³⁶ *Id.*

²³⁷ AM. BAR ASS'N, MODEL RULES PROF'L CONDUCT comment 4 to Rule 1.3 (2006), available at http://www.abanet.org/cpr/mrpc/rule_1_3_comm.html (last visited Sept. 21, 2006).

expressly terminates the relationship.²³⁸ Thus, if a patient believes the doctor-patient relationship exists, then the physician should offer only standard treatments, and never experimental research.

Performing research on subjects in the same venue, and within the same relationship, as their treatment, poses a threat to the patients' bodily integrity and autonomy.²³⁹ The protection of these rights should be vigorously guarded. The violation of this protection can result in devastating consequences to the patient/subject.

Applying the tenets of the Nuremberg Code helps clarify this problem. The first rule of the Nuremberg Code requires informed consent as an inviolate component of subject participation in research.²⁴⁰ Under rule one "the voluntary consent of the human subject is absolutely essential." For voluntary consent, the patient must: 1) have legal capacity to give consent; 2) be so situated so as to be able to exercise free choice; 3) have sufficient knowledge and understanding.²⁴¹ In order to exercise free choice, the subject must be free from: force, fraud, deceit, duress, overreaching, and other forms of constraint or coercion.²⁴² The issue of free choice is particularly relevant to treating physicians obtaining consent for a research project from their patients. The existing physician-patient relationship is a "form of constraint or coercion" on the patient/subject.²⁴³ This relationship makes the free power of choice an unreasonable assumption in research participation. Voluntary assent becomes impossible.

The interests of the parties and the nature of their relationship cause this loss of truly free choice. The physician-patient relationship is a relationship of trust under which the interests/intent of physicians is to cure or treat their patients. The physician is beneficent and the code of do no harm prevails. Physicians act only in the patient's best interest. Of course, this situation is the ideal, and there are exceptions. However, patients will act as if the relationship continues even as they become a subject. Their decision to participate will be made within this coercive physician-patient relationship and therefore cannot be truly voluntary.

The interest or intent of the investigator is quite different from that of the physician. The interest of the patient is no longer the only interest and often is not the preeminent interest of the physician/investigator. There are many interests of

²³⁸ AMERICAN MEDICAL ASSOCIATION CODE OF MEDICAL ETHICS OPINIONS ON THE PATIENT-PHYSICIAN RELATIONSHIP, E10.015 THE PATIENT-PHYSICIAN RELATIONSHIP, <http://www.ama-assn.org/ama/pub/category/4325.html> (follow "Current Opinions of the Code" hyperlink, then follow "E-10.00 Opinions on the Patient-Physician Relationship" hyperlink, and select "E-10.015 The Patient-Physician Relationship" hyperlink) (last visited Oct 24, 2006); *supra* § E-8.115 TERMINATION OF THE PHYSICIAN-PATIENT RELATIONSHIP, <http://www.ama-assn.org/ama/pub/category/4325.html> (follow "Current Opinions of the Code" hyperlink, then follow "E-8.00 Opinions on Practice Matters" hyperlink, and select "E-8.115 Termination of the Patient-Physician Relationship" hyperlink) (last visited Oct 24, 2006).

²³⁹ See *Beecher*, *supra* note 225 and accompanying text; LAFRANCE, *supra* note 226 and accompanying text.

²⁴⁰ *Nuremberg Code*, *supra* note 5, at Rule 1.

²⁴¹ *Id.*

²⁴² *Id.*

²⁴³ See Paul Ramsey, *THE PATIENT AS PERSON 1* (2d ed. 2002) (citing "Articles from the Nuremberg Trial").

investigators, which include obtaining or renewing grants, advancing science, receiving financial gain, getting promotions and achieving prestige. At minimum, these interests dilute the motivations of treatment and create a conflict of interest.

The practice of medicine changes depending on the individual patient's response to a particular intervention.²⁴⁴ If drug A does not have the desired effect, then the dose may be altered or a new treatment instituted. The timing of this change will vary from patient to patient, according to their specific condition and response.²⁴⁵ Scientific investigation is not so flexible.²⁴⁶ In most studies subjects are assigned to specific, predetermined protocols. These are set methods of treatment and diagnosis. If the trial is a randomized, controlled trial, there will be more than one arm or protocol of the study. Subjects will be assigned on a random basis.²⁴⁷ In many studies, one arm will be a control treatment or accepted practice.²⁴⁸ Often studies involve a placebo, which is no treatment. Placebo arms are thought by much of the scientific community to make it faster and easier to determine the efficacy of a new treatment,²⁴⁹ but this theory is debatable both scientifically and ethically.

Subjects in research protocols will not have the protocol altered for their benefit. The protocol is fixed, unless the subject withdraws from the study or if the study ends. The assignment of which arm of the study a subject is placed on is not a determination made in the subject's best interest. The randomization is in the interest of science to further knowledge. The scientific method is not a mechanism to act in the best interest of the individual subject, but a means to advance scientific knowledge.²⁵⁰ The argument is made that the acquired knowledge will help future patients and society. I submit that the advancement of knowledge, or the benefit of future patients, is never a justification to use an individual as a means to an end.²⁵¹

Physicians/investigators often hold a personal belief of which treatment is the best. Even if the evidence is inadequate to make the treatment a proven or accepted practice, most investigators have a preference for one arm of the experimental

²⁴⁴ Sprumont, *supra* note 137, at 552-54.

²⁴⁵ *See id.*

²⁴⁶ David A. Lenrow, *Randomized Controlled Trials in Interventional Spine: Perils and Pitfalls*, 6 PAIN PHYSICIAN 84 (2003).

²⁴⁷ K.F. Schulz et al., *Empirical Evidence of Bias. Dimensions of Methodological Quality Associated with estimates of Treatment Effects in Controlled Trials*, 273 JAMA 408, 408-12 (1995).

²⁴⁸ As required by the *Declaration of Helsinki*, *supra* note 117.

²⁴⁹ *But see* Martyn Evans, *Justified Deception? The Single Blind Placebo In Drug Research*, 26 J. OF MED. ETHICS 188, 189-190 (2000) (discussing the ethical problems of using placebos, specifically the use of "single blinding"); R.J. Levine, *The Use of Placebos in Randomized Clinical Trials*, 7 IRB REV. HUM. SUBJECTS RES. vol. 2, 1,2-3 (1985) (discussing problems with the use of placebos in randomized clinical trials).

²⁵⁰ *Belmont Report*, *supra* note 8, at part A(A).

²⁵¹ Morin, *supra* note 71, at 221 ("[T]o manipulate men, to propel them towards goals which [we]... see, but they may not, is to deny their human essence, to treat them as objects without will of their own, and therefore to degrade them. This is why to lie to men or to deceive them, that is, to use them as means for [our], not their own, independently conceived ends, even if it is to their own benefit, is, in effect, to treat them as sub-human, to behave as if their ends are less ultimate and sacred than [our] own..." "For [the nature] of men is that they are autonomous beings...then nothing is worse than to treat them as if they were not autonomous but natural objects... whose choices can be manipulated") (*citing* ISAIAH BERLIN, *Two Concepts of Liberty*, in *FOUR ESSAYS ON LIBERTY* 135, 136-37 (1969)).

protocol.²⁵² A familiar way to conceptualize this is by inquiring which arm of the protocol they would use themselves or recommend to a family member. This belief is not communicated to their patients/subjects, nor can this preference be given to them because it would violate the scientific validity of the study. This example illustrates the tension between the role of physician and investigator. Investigators, by the nature of scientific experimentation, cannot always act in the best interest of their patient/subject. They cannot alter the protocol or preferentially assign the favored arm of the study to the patient. They cannot change the drug dose or the drug itself. Scientific protocols are rigid, but patient care is not.

In seeking care from a physician, patients' interests and intentions seem clear. Patients go to the doctor to get well, to be treated, or to obtain information solely in their best interest. They trust in their physician. If they do not trust their physician, then patients go to another doctor or do not heed the doctor's advice. Patients trust in their doctor's professionalism,²⁵³ because doctors have knowledge that they do not have. Therefore, patients are on unequal footing with doctors. Patients assume that the doctor has no conflict that will affect their treatment; otherwise, they would not go to them. If patients and doctors were on equal footing concerning medical knowledge, the situation would be different.²⁵⁴ If it is assumed that patients would still go to the doctor, the relationship could be more of a partnership. No party would have the upper hand or undue influence on the other in their ability to make decisions. Disclosure and discussion with clear understanding by the patient would allow them to make a free choice but most patients are not in this situation.

There is a clear conflict of interest between the patient and the investigator. Patients want to be treated in their best interest and investigators want to advance science and achieve their professional goals. Viewing this, in the context of the inferior footing of the patient in the relationship with the physician, it is not reasonable to believe that the interests of the physician/investigator would not materially affect the interests of the patient. This conflict reinforces the violation of the fiduciary relationship when treating physicians become investigators and their patients / subjects.

Nearly all patients have substantially less knowledge than the physician to whom they go for help. This unequal footing and the nature of the relationship make it unreasonable to assume that patients can exercise free choice, when their physician recommends participation in a research project. The therapeutic misconception, the belief that treatment is being administered when the intervention is for research, is common.²⁵⁵ Even when patients sign consent for a research project, they still believe that they will gain at least some benefit. The doctor-patient relationship colors how patients make their decision on whether or not to participate in a study. The source

²⁵² Don Marquis, *How to Resolve An Ethical Dilemma Concerning Randomized Clinical Trials*, 341 NEW ENG. J. MED. 691, 691-93 (1999).

²⁵³ McClellan, *supra* note 40, at 91-97.

²⁵⁴ *Id.*

²⁵⁵ P.S. Appelbaum, *False Hopes and Best Data: Consent to Research and the Therapeutic Misconception*, HASTING CENTER REP., April 1987, at 20, 21; Letter from Niels Lynoe, Umea University Sweden to The New England Journal of Medicine, 344 NEW ENG. J. MED. 460, 460 (Feb 8, 2001); Amelia L. Schultz, *Are Research Subjects Really Informed?*, 23 W. J. MED. 76, 78-80 (1975).

of the suggestion impacts how the patient makes their decision. If the source of the suggestion is the treating physician, the subject loses the required voluntariness of informed consent.²⁵⁶

The situation of treatment differs in that the doctor does not have any conflict of interest and their suggested treatment is only in the patient's best interest. There are exceptions to this case, including doctors with financial interests in pharmaceuticals or devices. The reliance of the patient on the physician's beneficence and professionalism is not misplaced. It is unrealistic to believe that, by any reasonable amount of consultation, a patient can be brought up to the level of knowledge of the physician. In decision making patients always rely to some degree on their trust in physicians. It has been said that physicians can obtain consent from patients merely by how they present the alternatives, risks, and consequences.²⁵⁷

Separating the role of physician and investigator and dispelling the therapeutic misconception has been suggested as a solution to the tension of this dual role of physician and investigator.²⁵⁸ Even with an express notification, that the intervention is experimental and that there will be no benefit, patients will still believe that they will have a possibility of benefit. Like lawyers, doctors cannot just take off their professional hat when it suits their interest. Professionals cannot unilaterally change their relationship with clients or patients. The doctor-patient relationship is based on the patient's belief that the physician acts in their best interest and to dispel this belief is to dissolve the relationship. The dual role cannot be undertaken without violating the free will of the patient and violating the Nuremberg Code. Voluntary consent cannot be obtained.

Vulnerable populations have their participation limited or are excluded from participation in experimentation because it is believed that they do not have the ability to exercise free will.²⁵⁹ Patients go to the doctor because they have some illness, are afraid, are in pain or are dying. They are vulnerable. They are in a position of inferior knowledge and seeking help from a person with expertise. The sicker the patient, the more pain they feel, the more vulnerable they become. The less one understands and the less treatment available, the more vulnerable patients become to opportunistic physician-investigators. Desperate hopes are easily manipulated. I believe that patients, like the recognized vulnerable populations, cannot exercise free, voluntary choice due to their situation and relationship with their physician.

The interests of the subject are often different from those of the patient. There are a variety of possible motivations of subjects. Some are subjects unknowingly; they believe they are being treated. For some it is the only way to receive new or novel treatments. These treatments may not be available outside of research protocols or the subject may not be able to afford them. They may believe it is in

²⁵⁶ See *id.* (indicating that the expectation of treatment clouds the ability to make a free decision).

²⁵⁷ Henry K. Beecher, *Some Guiding Principles for Clinical Investigation*, 195 J. AM. MED. ASS'N. (13), 1135, 1135 (1966); cf. F. J. Ingelfinger, *Informed but Uneducated Consent*, 87 NEW ENG. J. MED. 465, 465-66 (1972) (explaining that informed consent in actuality is impossible and the patients only real protection comes from the doctor).

²⁵⁸ Franklin G. Miller, *supra* note 71, at 1449-54.

²⁵⁹ *Common Rule*, *supra* note 27, at subparts B, C and D.

their best interest. Some people become subjects for financial gain, for payment. Often they 'volunteer' even if it is not in their physical or mental best interest.²⁶⁰ These conflicts between the subject and the patient create interesting problems. The issue pertinent here is that the duty of the physician is to treat the patient in their best interest. They should be advising patients on the proven course of action in their best interest. They should not take advantage of potential subjects based on these motivations. The roles of investigator and treating physician must be separate and distinct. These roles must be performed by separate individuals. The physician must not have any interest in the study, nor should they be recommending participation or obtaining consent for studies. The line between suggesting studies to patients and informing them of their existence is a difficult one. Physicians should not cross the line to researcher with their patients. They should not refer patients to any study in which they have a financial interest or as a co-investigator or otherwise. The nature of the physician-patient relationship will have an undue influence on the patient. Patients believe that the research is in their interest and that there is a likelihood of benefit but investigation is to elucidate the unknown. If there were a known benefit the project would be treatment, not research.

PART V: SUMMARY

I have argued for a per se rule prohibiting treating physicians from assuming the dual role of researcher with their patients. The current regulations and the proposed changes do not adequately address the breach of fiduciary duty and the inability of the subject/patient to give voluntary, informed consent. The relationship between doctor and patient is unusual in that patients trust physicians with their life and well being. Patients make their decisions regarding treatment with limited knowledge, because of their belief that the motivation of the physician is aligned with their best interest. That common goal is lost when the physician becomes the researcher. The stakes are too high and the knowledge of the negative consequences too disparate to assume that patients can separate advice from their physician acting in the dual role of researcher. The dichotomy of the roles, with their diverse interests, will not be understood or appreciated by most patients. Patient's trust will be misplaced, resulting in the loss of their ability to exert their free will. The voluntariness required for their consent to human research will be lost.

In the health care arena the doctor-patient relationship requires a much higher degree of professionalism, than any other relationship. Nurses could, in most situations, recruit patients for research, without disrupting their ability to give voluntary informed consent. Most other ancillary care providers do not engender the degree of trust and professionalism present in the doctor-patient relationship. What would remain important is that the patient/subject's treating physician, remains the physician to a potential research subject. They should remain in the position of being able to offer unbiased advice to their patients, to help direct choices of treatment solely in the best interest of the patient. The treating physician would then

²⁶⁰ See generally Paul McNeill, *A Response to Wilkinson and Moore Paying People to Participate in Research: Why Not?*, 11 *BIOETHICS* 390 (1997); Craig Fry & Robyn Dwyer, *For Love or Money? An Exploratory Study of Why Injecting Drug Users Participate in Research*, 96 *ADDICTION* 1319 (2001).

be available to consult with researchers regarding possible enrollment of their patients in research projects. This is analogous to lawyers with a conflict sending their clients to independent counsel.

Science progressed an immeasurable distance in the fifty-eight years since the Nuremberg Code. The tenets of ethical research, however, remain the same. The changes in how scientific investigation is undertaken and funded have brought the ethics of human experimentation to the forefront once again. The coercive nature of the doctor-patient relationship, and the unusual degree of trust that patients put in their physicians, creates a fiduciary relationship. The current procedural and substantive human research protections are inadequate. They only protect the subject with respect to disclosure, and to a lesser degree, understanding. There are currently no procedural or substantive protections for the voluntariness of the assent to be a subject, unless you are in a designated vulnerable population. The time to act to protect basic human rights is now. Free will or voluntariness of informed consent remains essential to ethical research. This is not addressed by the current regulatory scheme or by the prior NBAC recommendations. The protection of human subjects in experimentation requires a per se rule prohibiting treating physicians from assuming the dual role of investigator. Without such a rule patient/subjects lose the voluntariness required for free informed consent.