
1992

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Recommended Citation

Elizabeth R. McGuire, *An Entitlement of Veterans Affairs Medical Patients to Vulnerable Population Status for Human Medical Research*, 2 Health Matrix 259 (1992)

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Notes

THE ENTITLEMENT OF VETERANS AFFAIRS MEDICAL PATIENTS TO VULNERABLE POPULATION STATUS FOR HUMAN MEDICAL RESEARCH.

Elizabeth R. McGuire†

INTRODUCTION

“RESPECT FOR PERSONS requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided when adequate standards for informed consent are satisfied.”¹ Informed consent is the key to addressing the increased vulnerability of special populations when they are used in human medical research. In some cases, prospective subjects for human medical research are not in a position to give informed consent because they are not autonomous and, therefore, not capable of the independent decisionmaking necessary to consent. Persons incapable of giving informed consent are unlikely to be able to protect their own interests.² Their diminished capacity to protect themselves makes them “vulnerable.”³ The ethical principle of respect for persons,⁴ imposes a special duty with respect to these “vulnerable” persons “to the extent that their autonomy is limited, we show respect by protecting them from harm.”⁵

While various methods of categorizing “vulnerable” populations

† This note was written under the supervision of Maxwell J. Mehlman, Professor of Law, Case Western Reserve University School of Law. Special thanks goes to the members of the Wade Park VA IRB, of which I was gratefully a member. The views expressed herein are solely the author's.

1. Belmont Report, 44 Fed. Reg. 23192-23195 (1979). THE NATIONAL COMMISSION, THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH (The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, April 18, 1979) [hereinafter BELMONT REPORT].

2. Protection of Human Subjects, 38 Fed. Reg. 31738 (1973).

3. ROBERT J. LEVINE, ETHICS & REGULATION OF CLINICAL RESEARCH 72, (2nd ed. 1986).

4. *Id.* at 15-16.

5. *Id.* at 97.

have been advanced, each method attempts to identify "individuals as vulnerable or less advantaged in ways that are relevant to their suitability for selection as subjects."⁶ A two-step process has evolved for managing vulnerable populations. First, the population must be identified and evaluated as particularly vulnerable to problems that might arise when members of that group participate in medical research. Second, after a group has been identified, the regulatory agency must determine the means necessary to provide additional protection for the group. This note applies this two-step process to medical patients of the Veterans Affairs ("VA").

VA medical patients constitute a unique and easily definable group of people. The veteran using the VA system often does so because he has few other viable alternatives for affordable medical care. Once in the system, veterans relying on the VA for medical care may become subjects in biomedical and behavioral research.⁷

This note considers whether those who regularly depend on the VA system for their medical care should be classified as a vulnerable population, deserving of additional protection designed to fully insure their informed consent to participation in human medical research. First, for those less familiar with the informed consent process, basic concepts significant to the ethical use of humans in medical research must be considered; the historical development of consent requirements in both clinical medicine and research examined, and the development of federal policies protecting human subjects in medical research reviewed. Second, the note examines the identity of characteristics of vulnerable groups. Finally, the reasons for identification and immediate inclusion of the VA patient as a vulnerable group are considered.

I. PHILOSOPHICAL FOUNDATIONS OF INFORMED CONSENT

Respect for autonomy, justice and beneficence are the three founding ethical principles relevant to the issues of human medical research and informed consent. These principles provide the basis for more specific rules and requirements like those found in the American professional codes of clinical medicine and research eth-

6. *Id.* at 72. Another definition of vulnerable groups can be "those who are relatively (or absolutely) incapable of protecting their own interests. *Id.*

7. Oliver E. Meadows, *The Department of Veterans Affairs Health Care System and National Health Care*, 66 *ACAD. MED.* 744, 744 (1991).

ics discussed later.⁸ The principle of respect for autonomy demands that people "be free to choose and act without controlling constraints imposed by others."⁹ Beneficence requires physicians and researchers to "do good" for the patient-subject and prevent harm to that person.¹⁰ The principle of justice can be viewed alternately in comparative or non-comparative concepts. Non-comparative justice requires identification of what is due to a particular person "without regard to the claims of others", while comparative justice demands that people in "equal" positions be treated "equally" and those who are "unequal" be treated differently.¹¹ Although they overlap to some degree, these principles are distinct and must be considered separately when evaluating specific rules and behaviors.

A. Developments Leading to Consent Requirements in Clinical Medicine

The Hippocratic Oath, the historic foundation of guidance for medical ethics, requires physicians to choose measures to benefit the sick according to the individual physician's ability and judgment.¹² The Hippocratic Oath fails to address adequately the principle of autonomy and the attendant need for communication between physician and patient.¹³

"Informed consent" appeared as an issue in American medicine in 1957 when a California appellate court, in *Salgo v. Leland Stanford Jr. Univ. Bd. of Trustees*, stated that physicians violated a duty to their patients when they withheld any information necessary to form the basis of intelligent consent by the patient to the proposed treatment.¹⁴ The physician's duty to disclose was reviewed by the

8. RUTH R. FADEN & TOM L. BEAUCHAMP, A HISTORY AND THEORY OF INFORMED CONSENT 5 (1986).

9. *Id.* at 8.

10. LEVINE, *supra* note 3, at 16.

11. *Id.* at 17.

12. Robert M. Veatch, *Medical Ethics: An Introduction*, in MEDICAL ETHICS 1, 7-8 (Robert M. Veatch ed.) (1989). This early expression of the ethical principle of beneficence required the physician to balance risks and benefits in a way similar to modern day risk-benefit assessments. FADEN & BEAUCHAMP, *supra* note 8, at 216. A risk-benefit ratio analysis will determine the degree and likelihood of both injury and benefit to a given person. BERNARD BARBER, INFORMED CONSENT IN MEDICAL THERAPY AND RESEARCH 3 (1980).

13. *Id.* at 61. See also Judith C. Areen, *Bioethics and Law: The Second Stage: Balancing Intelligent Consent and Individual Autonomy. The Marks Memorial Lecture for 1988-89*, 31 ARIZ. L. REV. 447, 449 (1989). The treatise that accompanied the Hippocratic Oath expressly advised physicians to conceal information from the patient while treating him. *Id.*

14. 317 P.2d 170, 181 (Cal. Ct. App. 1957). The *Salgo* court found that physicians treating a patient who suffered permanent paralysis following a diagnostic aortography, were negligent both in their performance of the procedure and in failing to inform him of the

Kansas Supreme Court in *Natanson v. Kline*, when it held that the individual is the master of his own body.¹⁵ The court found that "the duty of the physician to disclose, however, is limited to those disclosures which a reasonable medical practitioner would make under the same or similar circumstances."¹⁶

The nature and scope of this disclosure requirement was further defined in *Canterbury v. Spence*, where the court distinguished the physician's duty to disclose from the patient's right to comprehend.¹⁷ The *Canterbury* court found that the physician's duty to disclose information to the patient was based on the patient's right of self-determination provided by law, and that the duty required all information *material* to that decision be disclosed.¹⁸ The *Canterbury* court noted that in the "duty to disclose cases, the focus of attention is more properly upon the nature and content of the physician's divulgence than the patient's understanding or consent" and that "the physician discharges the duty when he makes a reasonable effort to convey sufficient information although the patient, without fault of the physician, may not fully grasp it."¹⁹

To summarize, the modern doctrine of informed consent in clinical medicine is rooted in the premise that adults have the right to decide what is to be done to their bodies. Self-determination has evolved into the informed consent choice which includes adequate patient knowledge of the factors involved in treatment, including the alternatives and risks of the proposed therapy.²⁰ Disclosures

paralysis risk. Likewise, the court held that the physician may not minimize the known dangers of a procedure or operation in order to induce his patient's consent. *Id.*

15. 350 P.2d 1093 (Kan. 1960). One aspect of the physician's alleged negligence was the failure to warn the patient of injuries possible from cobalt treatment. See also Cathy J. Jones, *Autonomy and Informed Consent in Medical Decisionmaking: Toward a New Self-Fulfilling Prophecy*, 47 WASH. & LEE L. REV. 379, 389 (1983). Not discussed by that court were the meanings of full disclosure, therapeutic privilege, the bounds of physician discretion when making less than full disclosure and the underlying basis for the doctrine of informed consent. *Id.*

16. *Natanson*, 350 P.2d at 1106. Although the cause of action required that the issue be evaluated from the patient's perspective, on the premise of a patient's right to self-determination, the court evaluated patient consent in light of the physician's duty to disclose certain information. *Id.* See also Jones, *supra* note 15, at 391.

17. 464 F.2d 772 (D.C. Cir. 1972).

18. *Canterbury*, 464 F.2d at 786. The *Canterbury* court defined "materiality" as that information to which a reasonable person would attach significance in deciding whether or not to refuse the proposed treatment. *Id.* at 787, (quoting Waltz & Scheuneman, *Informed Consent to Therapy*, 64 Nw. U.L. REV. 628, 640 (1970)).

19. *Id.* at 780 n.15.

20. Gerald F. Tietz, *Informed Consent in the Prescription Drug Context: The Special Case*, 61 WASH. L. REV. 367, 370 n.20 (1986). As the use of informed consent within the clinical situation has traditionally been used to protect patients from risky procedures that

limited to what a reasonable practitioner would make in the circumstances (*Natanson*) and what a reasonable person would find material (*Canterbury*) have provided an "objective" standard of causation for the tort remedies provided in the common law. This objective standard requires the plaintiff to prove that a reasonable person would have declined treatment after being made aware of additional material facts.²¹ In contrast, a subjective standard would focus on the effect of additional information on the decision of the plaintiff-patient to undergo a particular therapy.

B. The Development of Ethical Consent Requirements in Research Medicine

This section first examines the inherent differences between the consent requirements needed for clinical medicine and clinical research, and then reviews the historical development of ethical consent requirements unique to the research setting and explores the reasons why people can be particularly susceptible to outside influences that deny this right to free consent.

1. Inherent Differences Between Research and Clinical Medicine

Human medical research is inherently different from clinical treatment. Phase I drug studies of pharmaceutical manufacturers exemplify the traditional class of "nontherapeutic research" on healthy volunteers.²² In these human studies, which are typically preceded by favorable animal experimentation, researchers study pharmacokinetic drug parameters and side effects of various dosages.²³ Research subjects are usually healthy volunteers who receive financial rewards and expect no particular therapeutic benefit from study participation.²⁴

In contrast, clinical trials do anticipate therapeutic benefit to research subjects. Nonvalidated, or investigational, procedures for a

result in physical injury, generally the law has denied "recovery for inadequate disclosure in the absence of bodily harm." Anne T. Corrigan, Note, *A Paper Tiger: Lawsuits Against Doctors for Nondisclosure of Economic Interests in Patients' Cells, Tissues and Organs*, 42 CASE W. RES. L. REV. 565, 579 (1992) (quoting Alan Meisel, *A "Dignitary Tort" as a Bridge Between the Idea of Informed Consent and the Law of Informed Consent*, 16 L. MED. & HEALTH CARE 210, 211 (1988).

21. *Id.*; See Tietz, *supra* note 20, at 374.

22. LEVINE, *supra* note 3, at 8, 23.

23. Dale L. Moore, *Recurrent Issues in the Review of Medical Research on Human Subjects*, 1 ALB. L.J. SCI. & TECH. 1, 5 (1991). These pharmacokinetic parameters include drug absorption, metabolism, and excretion. *Id.*

24. *Id.* Other examples of nontherapeutic research include discarded tissue studies and blood specimen studies. *Id.* at 6.

given disease are either new or in common use, but previously untested scientifically. When nonvalidated procedures are conducted within a rigid experimental protocol and the results compared to common clinical treatment practices for a particular illness in groups of patients afflicted with that disease, the resulting clinical trial traditionally has been labeled "therapeutic research."²⁵ Within a properly designed research protocol, either treatment regimen is equally valid at this initial point.²⁶ Random clinical trials ("RCTs") are a special form of either therapeutic or non-therapeutic research which use large numbers of subjects with different treatment modalities (including a placebo/no treatment modality) which are assigned randomly.²⁷

Even though clinical trials anticipate therapeutic benefit, the researcher has a conflict of interest in the patient's progress. The researcher is interested primarily in acquiring medical knowledge, not improvement of the subject's health.²⁸ When a patient is asked by his physician to participate in medical research, the patient may be confused by the physician's new role as research investigator. All physicians have the obligation, under the "principle of personal care," to provide for their patients' well-being and "take whatever measures are available to maximize the chances for a successful outcome."²⁹ But when a particular physician assumes the investigator's role, the obligation to optimize individual patient care is in direct conflict with the acquisition of medical knowledge.

The patient often fails to understand the significance of the physician changing his role to that of investigator. This misunderstanding, called "therapeutic misconception," leaves the patient believing that whatever treatment he will receive is the one "most likely to benefit him" and that there will be no major disadvantages to par-

25. *Id.* at 4-9.

26. Moore, *supra* note 23, at 7. This point is known as the "null hypothesis." *Id.*

27. LEVINE, *supra* note 3, at 185. The characteristics of random clinical trials include 1) control where two or more similar populations receive different therapies (or placebo/no therapy); 2) the determination of the significance of results through statistical analysis; 3) double-blinded execution, when feasible, so neither researcher nor patient is aware of the exact treatment; and 4) randomization, i.e., the therapies being compared are allocated among the subjects by chance. *Id.*

28. Paul S. Appelbaum, *Informed Consent and the therapeutic misconception*, in NIH READINGS ON PROTECTION OF BEHAVIORAL AND SOCIAL SCIENCE RESEARCH (Joan E. Sieber ed.) 35, 36 (1982). Although in theory, for the group of subjects in a well-designed project, the treatments are equally likely to be effective, in the individual case this is often untrue. Subjects may have had previous negative experiences with side effects, etc. of a given therapeutic regimen. *Id.* at 36.

29. Paul S. Appelbaum, et al., *False Hopes and Best Data: Consent to Research and the Therapeutic Misconception*, HASTINGS CENTER REPORT, Apr. 1987, at 20, 23.

participation in research.³⁰ Patients have difficulty believing that physicians “would either knowingly do something harmful to them, or would knowingly use them simply as a means for their own ends.”³¹ A common problem within medical research trials is that once an individual is assigned to a therapeutic arm of the protocol, his treatment will be rigidly defined by this protocol unless certain negative clinical changes occur. Even though both treatment regimens may be equivalent in the abstract for a particular patient, one may be found to provide superior clinical results. The physician’s freedom to make these changes during a course of therapy is seriously limited in the research situation. The investigator is faced with a conflict of interest because to change an individual’s therapy would invalidate the study.

Although patients are potentially placed at risk (that they will be assigned to a less effective treatment regimen) in order to gain clinical knowledge, society continues to encourage research using humans to continue the dramatic progression of medical knowledge gained through such experimentation.³² Because of this potential risk, however, consent given within a research setting must be scrutinized more closely than in clinical medicine.³³

2. Historical Developments

Regulations were promulgated to control the risks created by the growth of human medical research.³⁴ The more potentially harmful, intrusive, or experimental the procedure, the stricter and more numerous must be the safeguards to protect the individual.³⁵ One of the earliest statements on ethical experimentation originated with the war crimes trials following World War II. The Nuremberg trials exposed “barbarous” experimentation on humans by Nazi physicians. Judges responded by proclaiming the Nuremberg

30. *Id.* In reality, potential disadvantages accompany the potential gains to be derived from participation in research.

31. George J. Annas, *The Changing Landscape of Human Experimentation: Nuremberg, Helsinki, and Beyond*, 2 HEALTH MATRIX 131 (1992).

32. VEATCH, *supra* note 12, at 127.

33. Tom L. Beauchamp, *Informed Consent*, in MEDICAL ETHICS *supra* note 12, at 173, 177.

34. See *infra* text accompanying notes 93-104.

35. See e.g., GEORGE P. ANNAS ET. AL., INFORMED CONSENT TO HUMAN EXPERIMENTATION: THE SUBJECT’S DILEMMA 171 (1977). (listing guidelines for determining when extra protection is needed); see also Richard Delgado & Helen Leskovic, *Informed Consent in Human Experimentation: Bridging the Gap Between Ethical Thought and Current Practice*, 34 UCLA L. REV. 67, 67 n.1 (1986).

Code,³⁶ considered "one of the premier human rights documents in world history."³⁷ The Nuremberg Code is derived from "universal moral, ethical and legal concepts."³⁸ "Voluntary, informed, competent, and understanding consent is required by the first Principle of the Code, and Principle 9 gives the subject the right to withdraw from the experiment."³⁹ The Nuremberg Code provided a key definition of consent from which all subsequent codes and regulations are derived.⁴⁰ Voluntary consent was required, and the investigator was assigned the duty to obtain this consent.⁴¹ Thus, the Nuremberg Code replaced the concept that the professional's commitment to his subject should be the *sole* protection for that subject with the concept that the subject has a right to self-determination which, in turn, requires informed consent.⁴²

The continued discussion regarding appropriate disclosure in medical research expanded into the legislative arena during the post-war period after abuses similar to those banned by the Nuremberg trials were uncovered in America. A 1966 article in the *New England Journal of Medicine*, disclosing extremely risky experimentation conducted upon unknowing subjects, was the first of several examples uncovering unethical research behavior.⁴³ In the same year, the Board of Regents of the State University of New York censured several physicians for their role in the Jewish Chronic Disease Hospital Case in which subjects were exposed to live cancer cells as part of a research protocol.⁴⁴ Later, the Willowbrook State

36. Annas, *supra* note 31, at 121. This code is unique in that it has a moral and legal status different than others as it holds the status of representing international law. VEATCH, *supra* note 12, at 20.

37. Annas, *supra* note 31, at 120-121.

38. *Id.* at 121.

39. *Id.*

40. See generally, FADEN & BEAUCHAMP, *supra* note 8, at 153-158.

41. Protection of Human Subjects; Informed Consent, 44 Fed. Reg. 44,713-44,714 (1979) [hereinafter Informed Consent]. First on the list of ten basic principles produced as a result of the Nuremberg trials was that "the voluntary consent of the human subject was absolutely essential." See also FADEN & BEAUCHAMP *supra* note 8, at 155. The remainder of the Nuremberg code sets boundaries of acceptable research and describes the conditions under which a subject may volunteer. *Id.*

42. VEATCH, *supra* note 12, at 15. The Nuremberg code requires consent to be competent, voluntary, informed and understanding (or comprehending). ANNAS, *supra* note 31, at 121.

43. Jay Katz, *The Regulation of Human Experimentation in the United States - A Personal Odyssey*, 9 IRB: A REV. OF HUM. SUBJECTS RES. 1, 3 (1987). Henry Beecher, the author of the article, was an American physician who revealed multiple examples of unethical experiments in which patients were exposed to unacceptable risks without even knowing that they were experimental subjects, much less being advised of the potential risks. *Id.*

44. FADEN & BEAUCHAMP, *supra* note 8, at 162; see also Katz, *supra* note 43 at 2-3.

School studies, in which children were infected with hepatitis, were exposed in the 1970 book, *Research and the Individual*.⁴⁵ Finally, the Tuskegee Syphilis Study, where researchers withheld treatment for syphilis for decades, was another famous case where the rights of human subjects were knowingly violated over a prolonged period of time.⁴⁶

In the post- World War II period, organizations such as the American Medical Association as well as the federal legislature focused on the concept of the voluntary consent of the human subject.⁴⁷ Accordingly, Congress created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research ("National Commission").⁴⁸ National Commission duties included the creation of guidelines for informed consent and for ethical research regulation.⁴⁹ In response to this mandate, the National Commission suggested to the Department of Health and Human Services ("HHS") ways to improve the regulation of ethical human research. The Belmont Report, released in 1979 by the Commission, identified the ethical principles underlying human research and the subject areas to which they apply.⁵⁰ The principle of respect for persons prompted the National Commission to outline guidelines for informed consent;⁵¹ the principle of beneficence led

The patients were not informed that live cancer cells were being used or that the experiment was designed to measure their ability to "reject [these] foreign cells," a test unrelated to their normal therapeutic program. *Id.*

45. FADEN & BEAUCHAMP, *supra* note 8, at 163. At the Willowbrook school for mentally retarded children, newly admitted children were deliberately infected with infectious hepatitis in an effort to develop a prophylactic agent against this disease. *Id.*

46. *Id.* at 165. This study comparing the health and longevity of *untreated* syphilitic populations with similar disease-free populations continued decades after antibiotic treatments were available to cure this disease. The subjects, poor blacks, were never clearly informed, and they suffered a significantly higher rate of complications and morbidity from the disease than the control group. *Id.* at 166.

47. Informed Consent, *supra* note 41, at 47,715; in 1964, the Declaration of Helsinki expanded the Nuremberg philosophy and further refined ethical consent requirements. Alexander M. Capron, *Human Experimentation*, in *BIOLAW* 217, 233 (James F. Childress et al. eds., 1986). The World Medical Association adopted the Declaration of Helsinki in 1964. The Declaration was similar to the Nuremberg Code in that primary reliance was on the individual investigator. The difference between therapeutic and non-therapeutic research also was identified. *Id.* at 220.

48. FADEN & BEAUCHAMP, *supra* note 8, at 215-16.

49. *See id.* at 216. The Commission was specifically directed to explore the need for unique ethical research requirements within certain identified vulnerable groups; children, prisoners and the institutionalized mentally infirm. *Id.*; *See also* Informed Consent, *supra* note 41, at 47,713, 47,716.

50. *See* BELMONT REPORT, *supra* note 1, at 23, 194-95.

51. *See* Carol Levine, *Has AIDS Changed the Ethics of Human Subjects Research?*, 16 *LAW MED. & HEALTH CARE* 167, 168 (1988). Respect for persons incorporates the ethical

to risk-benefit assessment; and the principle of justice led to rules for the appropriate selection of subjects.⁵²

3. Why People Are Vulnerable

The National Commission was directed to identify the ethical requirements for informed consent in research involving various groups of subjects considered particularly "vulnerable."⁵³ The Nuremberg Code demanded voluntary consent that required that the person consenting have the legal capacity to give consent, be situated in a way that enabled him to consent freely without any form of constraint or coercion, and possess sufficient knowledge and comprehension of the subject involved.⁵⁴ The Nuremberg Code also identified the issue of special vulnerability when it recognized the ethical problems of using groups that could not consent to participate in research.⁵⁵ This premise that voluntary consent was essential for the conduct of ethical research created problems when researchers opted to use groups of individuals who cannot "consent" because they lack the freedom to voluntarily choose (prisoners), the legal capacity to give consent (children), or the ability to understand consent (the mentally infirm).⁵⁶

Several aspects of informed consent can be more clearly understood using a contract law model.⁵⁷ If informed consent is a special type of consensual contract, then analysis of the elements needed for the formation of a general contract may aid in understanding what is at risk when dealing with those groups considered particularly vulnerable to the consent process.⁵⁸ The law of contracts deter-

convictions that individuals should be treated as autonomous agents and that persons with diminished autonomy are entitled to protection. *Id.*

52. *Id.* People are treated in an ethical manner not only by respecting their decisions and protecting them from harm; but also by making efforts to secure their well-being.

53. LEVINE, *supra* note 3, at 235. In Public Law 93-348, Congress gave the National Commission a directive to identify what special requirements were needed in order to get the appropriate informed consent for research involving children, prisoners and the institutionalized mentally infirm. *Id.*

54. See generally FADEN & BEAUCHAMP, *supra* note 8, at 153-58.

55. LEVINE, *supra* note 3, at 235.

56. *Id.*

57. See *id.*, *supra* note 3, at 325-41. The disclosure and comprehension guidelines are clearly defined within the federal regulations. The remaining elements of legal competency and autonomy will be discussed below within the contract law model for vulnerable groups. *Id.*

58. See Diane K. Kjervik & Sandra J. Grove, *The Legal Meaning of Consent in Unequal Power Relationships*, 4 J. PROF. NURSING 192, 193 (1988). The legal concept of consent is that consent operates as a waiver of one's right to object to others' assertion of power over him or her. *Id.*

mines first who is capable and incapable of consenting to, i.e., entering into a contract. These determinations of capacity are based both on "public policy," as in the case where an entire class of persons is rendered incapable of contracting, and on case-by-case determinations based on particular circumstances involved. The law then determines, on a case-by-case basis, whether the circumstances render the particular "consent" so *involuntary* or *uninformed* as to be invalid.⁵⁹ This definition contains two key elements: the ability or capacity to contract and the voluntary choice (volition) to contract.⁶⁰ To fall within its parameters, a person must possess both the ability to engage in the cognitive powers of reasoning and the ability to exercise the volitional powers of choice. Without these basic capacities, actual consent is irrelevant because the person is incapable of contracting *ab initio*. The capacity to consent is merely a baseline as it only requires that one have the inherent capability to choose and not that he has actually done so.⁶¹

A contract will be found to be invalid if the second element of voluntary or autonomous choice can be shown to be lacking.⁶² Autonomy requires that a person act intentionally,⁶³ with understanding⁶⁴ and free from controlling influences.⁶⁵ "Intentionally" is defined in terms broad enough to include situations where the individual consciously chooses a course of action even though he is only tolerating the negative aspects of the consequences.⁶⁶ Actions cannot be both autonomous and controlled by outside influences, so that when outside forces control someone's decision, these forces invariably serve to deny him the right to act in his own self-interest.⁶⁷

Because autonomy, in the absolute terms mentioned above, may be too idealistic to achieve in many real-life situations, informed consent is considered to occur when a person possesses substantial

59. *Id.* at 193-94 (emphasis added).

60. *Id.* at 194.

61. *Id.*

62. *Id.* The Nuremberg Code *also* demanded autonomy when it dictated that "[a] person . . . involved should be so situated as to be able to exercise free power of choice without the intervention of any element of fraud, deceit, duress, over-reaching or other ulterior form of constraint or coercion." Nuremberg Code Principle 1. See LEVINE, *supra* note 3, at 425.

63. FADEN & BEAUCHAMP, *supra* note 8, at 242-48.

64. *Id.* at 249-55.

65. *Id.* at 238.

66. *Id.* at 242-48. An example of negative outcomes that some might be more willing to endure would be a disfiguring scar for a person undergoing surgery in the hopes of curing cancer. *Id.*

67. *Id.* at 256.

understanding and, without substantial external control, intentionally authorizes a professional to do something for him.⁶⁸ When a person's level of understanding and freedom in informed consent situations is equivalent to what he would have when making a contract or accepting a job offer, then substantial autonomy has been achieved.⁶⁹

Contract law addresses impediments to the ability to make a voluntary or autonomous choice. It identifies the two major impediments as "the law of duress" and "the law of undue influence."⁷⁰ While duress affects free choice through coercive, threatening pressure, undue influence coerces people with rewards or promises.⁷¹ Withholding information, playing on emotions, or presenting constraints in a particular manner can effectively control a person's behavior to the extent that it prevents him from being able to make a free choice.⁷²

Personal autonomy requires freedom from external controls that rob the person of independence.⁷³ While it may be acceptable to influence a person's behavior, one cannot *control* another's behavior and remain within the ethical limits of informed consent.⁷⁴ This distinction explains why actions *substantially* autonomous rather than absolutely autonomous satisfy the ethical requirements of informed consent. Given this distinction, some influences are tolerable while others exceed ethical limits. The three types of external influence that will be discussed are coercion, persuasion and manipulation.

"Coercion occurs if one party intentionally and successfully influences another by presenting a credible threat of unwanted or avoidable harm so severe that the person is unable to resist acting to avoid it."⁷⁵ The person subject to coercive influences will choose to participate in research not because he is willing to endure the inconvenience or discomfort for altruistic reasons, but to avoid a greater harm.⁷⁶ This type of influence is never compatible with the auto-

68. TOM L. BEAUCHAMP & JAMES F. CHILDRESS, *PRINCIPLES OF BIOMEDICAL ETHICS* 79-81 (3d ed.) at 76 (1985).

69. FADEN & BEAUCHAMP, *supra* note 8, at 240-41.

70. *Id.*

71. Ruth Macklin, "Due" and "Undue" Inducements: On Paying Money to Research Subjects, 3 *IRB, A REV. OF HUM. SUBJECTS RESEARCH* 1, 1 (1981).

72. See, e.g., Beauchamp, *supra* note 33, at 188.

73. *Id.* at 256.

74. FADEN & BEAUCHAMP, *supra* note 8, at 258.

75. *Id.* at 339.

76. *Id.* at 338-343.

mous action required for informed consent.

Persuasion, in contrast, is defined as influence which never controls behavior to the extent that it denies the person the ability to make an autonomous choice. Persuasion can be defined as "the intentional and successful attempt to induce a person, through appeals to reason, to freely accept, as his or her own, the beliefs, . . . advocated by the persuader."⁷⁷ Because a person subject to persuasion is not denied his self-directed behavior, this form of influence does not violate personal autonomy.

Manipulation, the third category, falls between coercion and persuasion. Manipulation will often influence another's behavior to a degree which denies his self-directed or autonomous behavior. Manipulation through rewards or other beneficial offers (i.e. manipulation of the options) can be the most difficult form to guard against.⁷⁸ This concept is virtually identical to the contract law concept of undue influence previously discussed.⁷⁹

The affirmative act of "consent" is the last stage of the process where a potential subject "signifies his willingness to become a subject by consenting."⁸⁰ This process, which usually involves the signing of a consent form, is similar to signing a contractual agreement.⁸¹ Effective informed consent requires that the signing indicates an active authorization that is more than passive express agreement or compliance with an arrangement.⁸² When the contract signed is between two parties of extremely unequal power, the more powerful of the two, the investigator in the research context, is also considered to be acting as a fiduciary for the other party.⁸³ The need of a fiduciary, such as the physician or investigator, to protect the best interests of the subject potentially conflicts with the research goals of advancing medical knowledge.⁸⁴ Conflicts of interests cannot be ignored since autonomy is considered to be the

77. *Id.* at 347.

78. *Id.* at 354-56. The three basic categories of manipulation include manipulation of options, manipulation of information and psychological manipulation. *Id.* at 354-65.

79. Macklin, *supra* note 71, at 6. For example, when a subject feels compelled to do something deceitful, such as giving false medical information, in order to qualify for research participation, then the external influence to include him within this study is "undue." An undue influence is a promise or reward which is excessively high with respect to that patient's situation and may result in the subjects lying, for example, to insure participation in research. *Id.*

80. LEVINE, *supra* note 3, at 123.

81. *Id.*

82. BEAUCHAMP & CHILDRESS, *supra* note 68, at 76.

83. Kjervik & Grove, *supra* note 58, at 123.

84. Appelbaum, *supra* note 29, at 26.

element most affected when the two parties are of unequal power.⁸⁵

In addition to instances of intentional manipulation, there is a form of unintentional manipulation equally capable of denying autonomous choice to participate in research. This unintentional manipulation occurs through "role constraints." "[A] person's role can carry with it certain expectations for behavior and consequent intentional actions that function to limit or constrain that person's autonomous expression."⁸⁶

People within certain roles are capable of manipulating situations to an extent sufficient to prevent autonomous decisions even when there is no intention to do so.⁸⁷ While this occurs throughout life, for the purpose of this discussion, role constraint is important because it causes patients to act in ways that they otherwise would not act if not under a peculiarly intense and oppressive situation resulting from a patient's dependent status, especially if he was particularly vulnerable.⁸⁸ Often the person placed in a position of relative powerlessness reacts by becoming passive and empowering the authority figure to control and even dictate his personal decisions and actions in ways he would ordinarily not tolerate.⁸⁹ Autonomy was also the element considered at risk within the contracts model when there was a great degree of inequality between the parties.⁹⁰ These basic concepts can be directly applied to the informed consent situation in which the investigator's position of significantly greater power may act as a role constraint deny free choice to participate in research for.

If interpretation of research-related informed consent for vulnerable populations would use the same objective reasonable person standard that has been used for other, less vulnerable groups, the peculiarities of the individual subject's protection will be entirely lost. It is imperative to remember that it is the individual's subjective interpretation of a situation that is important when determining whether the particular situation has deprived an individual of his

85. Kjervik & Grove, *supra* note 58, at 192.

86. FADEN & BEAUCHAMP, *supra* note 8, at 368.

87. *Id.* The acceptable alternatives to a situation may be constrained either because people "intentionally structure particular encounters with that person in manipulative ways" or "social or cultural arrangements and expectations for the role the person assumes can function as constraints on autonomous expression." *Id.*

88. *Id.* at 369. General circumstances of societal constraints must be distinguished from particular situations. Examples cited were that of hospitalized patients, prisoners, students and employees. *Id.*

89. *Id.*

90. Kjervik & Grove, *supra* note 58, at 192.

right to choose research participation voluntarily. Because vulnerable people are more susceptible to coercive threats or manipulation, they will lose the protection against this behavior if the situation is viewed from the traditional objective, "reasonable person" standard used for others in both research and clinical situations.⁹¹

People within vulnerable groups should not be considered to be objectively reasonable and should not be evaluated as if they are. If an objective standard is to be used to measure consent in these cases, the standard must be re-formulated to account for the subjects' greater vulnerability. The standard should ask how a "reasonable person who is particularly vulnerable to manipulation or coercion because of his excessively dependent status" would view the situation in which the person is asked to participate in research. This change in criteria would better guard against the dramatically greater possibility of overt or passive manipulation in the form of role constraints.

C. Formal Federal Policies Regulating Human Medical Research

Informed consent in the research setting is primarily controlled through federal statutes and regulatory interpretation of these statutes.⁹² As a consequence, the protection provided by informed consent in medical research, as defined by these various regulatory bodies, has moved away from compensation for previously inflicted injuries to a prospective system designed to prevent these harms from occurring.⁹³ The requirement for a patient's express consent to research participation was part of the changes to the *Food, Drug and Cosmetic Act* in the Drug Amendments of 1962, which also refined the statutory power of the Food And Drug Administration ("FDA") to regulate drug research.⁹⁴

Another unique feature protecting informed consent within the

91. FADEN & BEAUCHAMP, *supra* note 8, at 343.

92. PAUL S. APPELBAUM ET AL., *INFORMED CONSENT, LEGAL THEORY AND CLINICAL PRACTICE* 211 (1987). While clinical consent to medical treatment is largely a creature of case law, with later statutory modifications, research consent has been almost exclusively shaped by professional codes, statutes and administrative regulations. *Id.*

93. Corrigan, *supra* note 20, at 581.

94. Informed Consent, *supra* note 41, at 44,714. These amendments were partially a result of the thalidomide drug disaster. Pregnant mothers for whom thalidomide was prescribed had not been informed that they were taking an experimental drug or that its safety to their unborn fetus was unknown. The mothers who received this medication later gave birth to children with birth defects. See Katz, *supra* note 43, at 3. Federal Food, Drug and Cosmetic Act, as amended (§§ 201-902, 52 Stat. 1040 as amended; 21 U.S.C. §§ 321-392) (1970).

research setting was the creation of the requirement of prior approval of each research project by the local Institutional Review Boards ("IRBs") created by the 1962 Amendments.⁹⁵ The IRB fulfills its duty as a watchdog of patient's safety and rights by evaluating all research within the institution it encompasses.⁹⁶ The regulations specify the number and type of IRB members as well as the IRB's goals with respect to informed consent, risk assessment and appropriate research design.⁹⁷

The regulatory approach of the HHS and FDA, using the IRB at its heart, controls with tighter specifications for consent than does the common law tort protection offered for clinical medicine.⁹⁸ Although IRBs are considered to operate efficiently in general, the lack of a system for these decentralized bodies to share information and establish precedent in the resolution of difficult studies weakens the system.⁹⁹

The new FDA requirements led to similar regulation within the National Institutes of Health ("NIH").¹⁰⁰ In 1973, congressional hearings prompted additional protections in the National Research Act of 1974.¹⁰¹ The Secretary of the Health, Education and Welfare Department, (now the Department of Health and Human Services ("HHS")), was directed to establish IRBs at all institutions using the Department as a source of research funding, and to create

95. See Food and Drug Administration: Part 56 - Institutional Review Boards, 21 C.F.R. §§ 50, 56 (1991)[hereinafter Institutional Review Boards].

96. Moore, *supra* note 23, at 8. Subject risks are minimized by scrutinizing procedures for good research design and avoidance of unnecessary risks. The procedures for obtaining informed consent and the informed consent form itself are reviewed, as is subject selection criteria. The potential risks to subjects is weighed against the anticipated benefit to those subjects and the importance of the knowledge obtained. *Id.* at 8-9.

97. *Id.* at 11.

98. APPELBAUM, *supra* note 92, at 227.

99. *Id.* Other problems include the fact that the primary responsibility for obtaining informed consent is upon the principal investigator, that certain categories of research permit waivers of informed consent, and that the system lacks an effective remedy for violations. See also Delgado & Leskovac, *supra* note 35, at 76-79.

100. Protection of Human Subjects, 47 Fed. Reg. 52,880, 52,911 (1982) [hereinafter 1982 Human Subjects]. See also Katz, *supra* note 43, at 3. It was determined that future Public Health Service ("PHS") funding, sponsored through the NIH, would be forthcoming only if prior approval by the local IRB and procurement of informed consent by each principal investigator were obtained. LEVINE, *supra* note 3, at 146. With this NIH enactment, the mold for all subsequent regulation was set in a "decentralized, institution-based, prospective review of research, with informed consent explicitly required as part of the process of subject recruitment." APPELBAUM, *supra* note 92, at 217.

101. Pub. L. No. 93-348, 88 Stat.342 (1974). This statute established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. (1974-1978).

a basic framework for ethical human research in the United States.¹⁰² These regulations were later recommended by the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, in existence from 1980-1983,¹⁰³ to provide the basic framework for other agencies to adopt in their regulation of human research.¹⁰⁴

1. The HHS Model of Regulation

The HHS model of regulation, also known as the "Institutional Assurance System," is the dominant model for the protection of human subjects.¹⁰⁵ This system is applicable to situations in which a government agency, such as HHS, sponsors human research.¹⁰⁶ The HHS regulations stipulate that an institution receiving funds for research must provide satisfactory written assurance to the Secretary that it will comply with the requirements of 45 C.F.R. 46.¹⁰⁷ These regulations require prior review by the local IRB to determine if these governmental standards will be met.¹⁰⁸ Once local IRB and other institutional approval is acquired, the research proposal is sent to the federal agency from which funding is being sought.¹⁰⁹

2. The FDA Model of Regulation

The FDA operates under a fundamentally different model known as the "Retrospective System."¹¹⁰ The FDA does not sponsor drug research and, therefore, has only indirect control of the

102. Basic HHS Policy for Protection of Human Research Subjects, 45 C.F.R. § 46 (1991)[hereinafter Protection of Human Subjects]. See also Capron, *supra* note 47, at 234.

103. FADEN & BEAUCHAMP, *supra* note 8, at 221. This commission was authorized in November 1978 by the U.S. Congress and was first convened in January 1980 to continue the work of the National Commission on ethical issues that were of interest to the general public. Clinical treatment issues were the major focus, rather than recommendations about federal policies. *Id.* at 96-97.

104. THE PRESIDENT'S COMMISSION FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIORAL RESEARCH, PROTECTING HUMAN SUBJECTS, 67-71 (1981) [hereinafter PRESIDENT'S COMMISSION]. This recommendation was repeated in 1983 (See PRESIDENT'S COMMISSION, IMPLEMENTING HUMAN RESEARCH REGULATIONS, 8-10 (1983)).

105. FADEN & BEAUCHAMP, *supra* note 8, at 222.

106. *Id.* at 217-252. Approximately two dozen federal agencies fund research in a system similar to the HHS. *Id.*

107. Protection of Human Subjects, *supra* note 102, § 46.101.

108. LEVINE, *supra* note 3 at 325-28.

109. *Id.*

110. FADEN & BEAUCHAMP, *supra* note 8, at 202-04.

institution conducting the research.¹¹¹ Investigational drugs are those drugs being studied for human use but not yet approved by the FDA.¹¹² As a result, rather than obtaining prospective assurances of compliance to ethical standards through IRB scrutiny, the FDA reviews the adequacy of human subject protection retrospectively, during its approval procedure. The drug sponsor bears the responsibility to insure protocol compliance and IRB approval, and risks refusal of the application for a new product if the research in support materials is unethically produced.¹¹³

3. The VA System of Regulation

The Veterans Administration, now the Department of Veterans Affairs, is a health entity distinct from other United States health care. Its duties include the "four statutory missions of furnishing quality health care to veteran patients; conducting medical, health services, and rehabilitation research; educating and training health care providers; and acting as the backup health care system for the Department of Defense in time of war or national emergency."¹¹⁴ During the 1970's, the VA independently issued research guidelines similar, but not identical, to those issued by HHS.¹¹⁵ Not unlike the FDA, the statutory coverage for the VA system is independent but parallel to the HHS regulations and the National Commission recommendations.¹¹⁶ The VA, while attempting to comply with the recommendations of the National Commission, was free to interpret these recommendations in its own unique fashion.

Although forms used by the VA system initially were different than those mandated, by 1979 several changes had been made to comply with the new HHS recommendations.¹¹⁷ Although differ-

111. *Id.*

112. Moore, *supra* note 23, at 5 n.9. The term investigational is a term of art; "[b]efore a drug can be studied in humans, its sponsor must submit an Investigational New Drug Application to the FDA." *Id.* (quoting Kessler, *The Regulation of Investigational Drugs*, 320 *NEW ENG. J. MED.* 281, 282 (1989)).

113. Institutional Review Boards, *supra* note 95 § 50.103. *See also* Capron, *supra* note 47, at 148.

114. Meadows, *supra* note 7, at 744.

115. Marilyn T. Baker & Harvey A. Taub, *Readability of Informed Consent Forms for Research in a Veterans Administration Medical Center*, 250 *JAMA* 2646, 2646 (1983).

116. *See infra* note 110-113 and accompanying text.

117. Veterans Administration, Department of Medicine and Surgery, Circular 10-79-232 (September 25, 1979) [hereinafter VA Circular 10-79-232]. The additional information appearing in later forms included that required by 43 Fed. Reg. 51,559, providing information about compensation and treatment of injured clinical research participants for all projects supported by research funds from HHS. *See* Baker & Taub, *supra* note 115, at 2646. Prior to 1975, the consent form signed by subjects participating in human research within the VA

ences in form remained, the overall requirements were nearly identical.¹¹⁸

As the federal regulations developed within the HHS, FDA and VA (in addition to the other parallel agencies not at issue here), the requirements of these three major agencies continued to be intertwined. An example from a VA Department of Medicine and Surgery bulletin clearly shows the interrelationship: "VA investigators receiving HHS funds, whether by direct grant or through affiliated institution, must comply with both VA and HHS regulations. Many investigators will also have to comply with FDA regulations on clinical testing of new drugs and devices."¹¹⁹

The VA requirements differ from the HHS guidelines in certain respects which include several policies that are more restrictive. These differences include the VA policy of: prohibiting expedited review, which permits two IRB committee members to individually review a research protocol and approve it before the monthly meeting;¹²⁰ prohibiting the use of exempt research categories of research, such as education testing, which are not subject to HHS regulations are still subject to VA regulatory review;¹²¹ prohibiting the waiver of informed consent as an abbreviated consent procedure which changes or eliminates certain elements of informed consent;¹²² prohibiting "short form" written consent which allows oral presentation of the informed consent procedure to certain potential subjects;¹²³ and prohibiting cash payments to hospital inpatients.¹²⁴ Further, the VA requires multi-center cooperative research studies involving individual VA medical centers to obtain VA IRB approval

system was "VA Form 10-1086." In 1975, this form was revised to include an information sheet specific to a particular study. *Id.* at 2646. However, the investigator could waive the requirement for this signed consent if, in his professional judgment, it was not feasible or in the best interest of the patient to have this form signed. *Id.*

118. VA Circular 10-79-232, *supra* note 117. When the VA Circular 10-79-232 is compared to 45 C.F.R. 46 § 116 (1983), it can be seen that both contain similar requirements. The HHS regulations spelled out certain details more clearly. The VA required information regarding the purpose of the investigation, the procedures used, any known risks anticipated, benefits anticipated, alternate courses of action, the anticipated result if no therapy is undertaken and a statement that the subject may withdraw at any time without prejudice. *Id.*

119. Veterans Administration, Department of Medicine and Surgery, Interim Issue 10-81-44 (October 8, 1981). The purpose of this bulletin was to inform the individual VA centers of modifications to their Research Policy and Procedure Manual, M-3, Pt. 1, Ch. 1.

120. Protection of Human Subjects, *supra* note 102, § 46.110.

121. *Id.* § 46.101(2)(b).

122. *Id.* § 46.116 (c).

123. *Id.* § 46.117 (b)(2).

124. Office of Science and Technology; Proposed Model Federal Policy for Protection of Human Subjects, 51 Fed. Reg. 20,204, 20,217 (1986)[hereinafter Proposed Model Policy].

in addition to IRB approval of the other research center.¹²⁵

The VA position prohibiting expedited review, was codified by 1982.¹²⁶ This position is in contrast to the FDA and HHS, which have accepted the recommendations regarding expedited review by the National Commission.¹²⁷

4. The Common Rule¹²⁸

While the VA, historically, has been permitted to define its own parameters for medical research, if the research performed within the VA system is funded by the HHS or used FDA controlled pharmaceuticals or medical devices, other procedural rules also apply. This regulatory overlap was the impetus for the Office of Science and Technology Policy, Executive Office of the President, to follow through on the recommendations of the President's Commission to establish a Proposed Model Federal Policy for Protection of Human Subjects.¹²⁹ The "Model Federal Policy" sought to eliminate unnecessary duplication in the regulation of human medical research. On June 18, 1991, this Model Policy appeared as a final rule in the *Federal Register*.¹³⁰ This model policy has been designated "the common rule."¹³¹ A month later the FDA amended its rules to be in substantial compliance with the common rule.¹³²

Research investigators within the VA must comply with either the HHS Institutional Assurance system, the FDA Retrospective system, or both depending upon the research funding source. Additionally, VA researchers must also meet specific regulatory require-

125. *Id.*

126. Veterans Administration, Department of Medicine and Surgery, Circular 10-82-88 (May 25, 1982) [hereinafter VA Circular 10-82-88]. The prohibition of expedited review first appeared in VA Circular 10-82-88 and later was incorporated into the 1985 M-3, Pt. I, Ch. 9, 9.03. This later circular stated that although allowed by HHS and FDA regulations, any research using VA patients, resources or staff must submit to complete VA IRB and Research and Development review. *Id.*

127. Protection of Human Subjects, 43 Fed. Reg. 56,173-89 (1978).

128. Joan P. Porter, *The Federal Policy for the Protection of Human Subjects*, 13 IRB, A REV. OF HUM. SUBJECTS RESEARCH 4 (1991). The common rule, previously known as the Model Rules, replaced the 1981 version of Subpart A of the Department of Health and Human Services regulations known as 45 C.F.R. Part 46. *Id.*

129. *Id.* In May 1982, the chairman of Federal Coordinating Council for Science, Engineering, and Technology (FCCSET) consulted with the Office of Science and Technology Policy (OSTP) and the Office of Management and Budget with the goal of developing these model rules. *Id.*

130. Federal Policy for the Protection of Human Subjects; notices and rules, 56 Fed. Reg. 28002 (1991)[hereinafter Federal Policy Regulations].

131. Porter, *supra* note 128.

132. Federal Policy Regulations, *supra* note 130, at 28,025.

ments that the VA has established for investigators within its system, independent of outside or internal VA funding of the research. However, in 1986, during the initial proposal of the Model Federal Policy, the VA was recognized as unique; certain exceptions to the uniform rules were recognized at the outset. VA will continue intramural research and development practices of not permitting exempted research [§ 46.101(2)(b)] or expedited review (§ 46.110), not permitting waiver of informed consent [§ 46.116(c)] or "short form" written consent [§ 46.117(b)(2)], and not requiring written institutional assurances from VA medical centers [§ 46.103(a)]. Further, regarding cooperative research efforts under § 114, VA requires that each VA medical center which participates in a cooperative or multi-hospital project must obtain the approval of its own Human Studies Subcommittee for such research.¹³³

II. ETHICAL PRINCIPLES AS APPLIED TO VULNERABLE GROUPS—THE GENERAL ELEMENTS OF VULNERABLE GROUPS AND APPROPRIATE USE OF GROUPS CONSIDERED VULNERABLE

This section explains why VA medical patients should be considered a vulnerable group. First, I describe general characteristics of certain groups considered particularly vulnerable, and therefore unlikely to give effective informed consent, and the consequences of this increased vulnerability. Then I describe the VA medical patient and the VA system in which he receives his care. I also consider a similar patient population, prisoners, and discuss the development of regulation governing their use as research subjects. Finally, in the final section of the note, I argue that the the VA patient also should be considered a vulnerable group.

A. Who Is Considered Vulnerable

The National Commission identified several groups it considered to be vulnerable: prisoners, children and those institutionalized as mentally infirm.

The Belmont Report also included in its characterization of "vulnerable subjects" those who are economically disadvantaged.¹³⁴

Economically disadvantaged people are among those who could be characterized as a "captive population." Captive populations encompass those segments of American society who have come to rely

133. Proposed Model Federal Policy, 51 Fed. Reg. 20,204-17 (1986).

134. Belmont Report, *supra* note 1, at 23,197.

on the government for fundamental services.¹³⁵ Groups with the potential to be considered to be "captive" include young children, the incarcerated, the sick and the elderly.¹³⁶ Most people are dependent on others in some way. Captive populations, by definition, are so dependent upon the outside agency providing personal health services to them that they are subject to control by their caretakers.¹³⁷ Key ethical principles are threatened when this dependency causes an individual to fear he might forfeit his ability to remain within a desirable situation if he refuses to participate in research.

The broader and more significant the needs of this captive population, the greater the degree of dependency its members have on those providing assistance to them. People within captive populations, being highly dependent upon those providing needed services, are likely to be particularly susceptible to role constraints. Dependency relationships create a significant possibility that "role constraints" will compromise autonomous decisions.¹³⁸

Investigators often take advantage of the fact that some institutions accumulate large populations of individuals who are suitable as research subjects. They establish their research facilities in geographic proximity to these institutions to lower costs and ease the burdens of subject recruitment.¹³⁹ This phenomenon, known as "administrative availability," becomes a problem of comparative justice when the location results in a disproportionate use of certain economic or racial groups.¹⁴⁰

Although dependent subjects may fear the consequences of failure to cooperate with the physician/investigator,¹⁴¹ (as it is unlikely these patients would be actually denied future care if they refuse to participate in research), this perceived threat may not withstand the scrutiny of an objective, reasonable person standard. However, the reality of the continued treatment should not lessen the significance that the patient's perception may potentially cheat him of a voluntary choice to participate in research. Vulnerable groups are susceptible to role constraints which may operate to subjectively influence behavior so as to deny autonomy, even when the domi-

135. JENNIE J. KRONENFELD & MARCIA L. WHICKER, CAPTIVE POPULATIONS: CARING FOR THE YOUNG, THE SICK, THE IMPRISONED, AND THE ELDERLY 1 (1990).

136. *Id.*

137. *Id.* at 11.

138. *Id.* Examples include hospitals, military camps and prisons. *Id.*

139. *Id.*

140. See generally LEVINE, *supra* note 3, at 79-81.

141. *Id.* at 82.

nant person has no intention to do so. Persons who are totally dependent on an institution may submit to perceived or actual pressures to conform with institutional requests out of fear of being denied services or privileges. If the quality of medical care, staff attention, or living conditions are poor, an invitation to move into a special unit or research ward may be irresistibly appealing.¹⁴² If the objective standard were modified to account for the perceptions of these vulnerable people, measures to effectively counter these additional fears would be put into place to minimize the risk of violating the principles of ethical consent.

B. The Demands of Justice for Those Particularly Vulnerable

Comparative justice requires that increased vulnerability be countered with increased scrutiny in the selection of these subjects for use in medical research. Although the analysis of "respect for persons" and "justice" can be viewed separately, they become more interrelated within the vulnerable population than they are for the general subject population.¹⁴³

Because vulnerable groups are incapable of protecting their interests, the ethical principle of justice intervenes to question why these groups were chosen in the first place.¹⁴⁴ The goal is to identify individuals as vulnerable or less advantaged in ways that are relevant to their suitability for selection as subjects.¹⁴⁵ Justice is said to require activities designed to yield direct benefits to the individual subjects and to encourage research designed to benefit that particular population. There should be general restraint from involving the special populations in research irrelevant to their individual conditions or to conditions uncommon to their class.¹⁴⁶

The National Commission was concerned about the principle of justice, and it examined the requirements for equitable distribution of the benefits and burdens of research. It concluded that when a group of people are particularly vulnerable to undue influence, other less vulnerable subjects should be used whenever possible.¹⁴⁷

142. Natalie Reatig, *Research with Vulnerable Populations: Ethical Considerations and Federal Regulations*, in NIH READINGS OF BEHAVIORAL AND SOCIAL SCIENCE RESEARCH 181, 182-83 (Joan E. Sieber ed., 1983).

143. LEVINE, *supra* note 3, at 72.

144. *Id.* at 236. These people are "vulnerable or disadvantaged in ways that are 'morally relevant' to their research involvement." *Id.*

145. *Id.* at 72.

146. *Id.*

147. Karen Lebacqz, *Beyond Respect for Persons & Beneficence: Justice in Research*, 2 IRB: A REV. OF HUM. SUBJECTS RES. 1, 3 (1980).

If the primary reason for using a group of people is because they are more accessible, or administratively available, then not using other, less vulnerable subjects violates the principle of justice.¹⁴⁸ This conclusion was not based on a general concern for excessive research risks to the subjects.¹⁴⁹ Instead, the Commission focused on the equitable distribution of all research burdens.

To summarize, the use of vulnerable groups is not expressly forbidden by any ethical or regulatory parameters. Rather, the National Commission called for justification of any plan including vulnerable subjects, with this justification becoming increasingly difficult as the degree of risk or degree of vulnerability increases.¹⁵⁰ The plan must demonstrate that either the quality of the vulnerable person's consent is improved by increasing his capacity to consent (addressing respect for persons) or he is preferentially excluded and subjects more capable of consent are chosen (addressing justice).¹⁵¹

C. A Characterization of the VA Medical Patient in the VA System

The Belmont Report included in its characterization of vulnerable subjects those who are economically disadvantaged.¹⁵² As shown below, economic realities have forced VA patients to become a captive population in ways that may jeopardize their ability to voluntarily choose research participation.

1. The VA Medical Patient

Of the estimated twenty-seven million U. S. veterans,¹⁵³ only those falling within certain eligibility guidelines are entitled to receive health care from the VA medical system.¹⁵⁴ Today, the gener-

148. LEVINE, *supra* note 3, at 79. Certain institutions tend to accumulate significant populations suitable for specific types of research. Examples include hospitals, schools, welfare agencies and places of employment. Many investigators capitalize on this when they establish research units near these facilities. Although the investigator benefits from the lower expenses and minimized inconvenience in subject recruitment. Locating near vulnerable groups can result in an unfair share of the research burdens being placed on these populations. *Id.*

149. Protection of Human Subjects; Research Involving Prisoners, 42 Fed. Reg. 3076, 3078 (1977) [hereinafter Research Involving Prisoners].

150. LEVINE, *supra* note 3, at 87.

151. *Id.* at 236.

152. BELMONT REPORT, *supra* note 1, at 23,197.

153. John A. Gronvall, *Medical Care of Low-Income Veterans in the VA Health Care System*, 6 HEALTH AFFAIRS 167, 167 (1987).

154. *Id.* at 173; see also Veterans Administration, Department of Medicine and Surgery, Circular 10-86-71 (June 26, 1986)[hereinafter VA Circular 10-86-71].

ation of World War II veterans, constituting one third of living veterans, has now reached retirement age and is increasingly dying.¹⁵⁵ This growing population of elderly veterans is more likely to seek medical care from the VA system because of their age and impoverishment.¹⁵⁶

The veteran feels a sense of entitlement to the medical care the VA system provides for him, especially (but not exclusively) if his medical problem is service-related.¹⁵⁷ Notwithstanding this sense of entitlement, "The Veterans' Health Care Amendments of 1986"¹⁵⁸ established three groups of veteran entitlement/eligibility for VA hospital and nursing home care.¹⁵⁹ These parameters of entitlement have changed to a system where veterans previously secure in their medical care may no longer qualify.¹⁶⁰

VA medical facilities have the reputation "as health care providers of last resort [and] places where veterans go when they cannot receive care anywhere else."¹⁶¹ Only a small percentage of veterans

155. Harry Schwartz, *Fear of Change Could be VA's Undoing*, (April 1992) VA PRACT. at 53, 54.

156. Gronvall, *supra* note 153, at 174. The group of veterans age 65 and older will increase by 61% before the turn of the century. *Id.* at 167.

157. Iris F. Norstrand, *VA-Medical School Affiliations: An Unfair Partnership*, 262 JAMA 31 (1989). It is said that the primary goal of the VA system is "to care for him who shall have borne the battle." *Id.*

158. Pub. L. No. 99-272, 89 Stat. 26.

159. Veterans with service-related conditions, as well as low income veterans, have the highest entitlement (high priority-Category A) to hospital care. VA CIRCULAR 10-86-71. Hospital care is to be provided to veterans in the other two groups (Category B and C) if space is available. The law has established an income-based or "means test" for determining eligibility for medical care for veterans with non-service related medical conditions. If individual income exceeds the maximum allowed by the means test, care still may be provided if space is available and the veteran agrees to pay a co-payment. The law eliminated the existing eligibility of veterans age 65 and over to receive medical care based on age alone. *Id.*

160. Gronvall, *supra* note 153, at 173. The "means test" allows eligibility for category A veteran care if their income falls at or below prescribed income threshold levels of \$15,000 for single veterans and \$18,000 for veterans with one dependent. *Id.* For example, veterans with non-service related injuries, previously entitled to coverage automatically at the age of 65, must now also meet the "means test" eligibility requirements to be considered "high priority," or Category A, and receive that category's absolute entitlement to medical care. Categories B and C are "low priority," and medical care is provided to veterans in these categories only when available. *Id.* Before the 1986 amendments elderly veterans were automatically eligible because it was presumed that they were unable to pay for care. Also, before this amendment, veterans without service-related conditions "were eligible for VA medical care only if they stated under oath that they were unable to defray the cost of necessary hospital care elsewhere." *Id.* at 170. Certain veterans fall into a special exempt class automatically entitled to care without regard to income. The exempt classes include; ex-POWs, World War I veterans and VA pension recipients. *Id.* at 173.

161. James F. Burgess, Jr. & Theodore Stefanos, *Federal Provision of Health Care: Creating*

entitled to this care use it.¹⁶² The 1980 census found that only ten percent of veterans use the VA health care system.¹⁶³ Of this small group, a significant number have no alternative health care coverage.¹⁶⁴ Of those veterans within the population relying on the VA medical system who have other insurance, a significant number are covered by "non-private" types of insurance, such as medicaid or medicare.¹⁶⁵ Although these alternate programs allow him access to other health care facilities, the VA patient's lower income makes paying the large co-payments and deductibles imposed by those programs prohibitive, especially when compared to free VA medical care.¹⁶⁶ Thus, the typical veteran looking to the VA system for his care relies upon that governmental service and perceives that he is a "captive" to the system.¹⁶⁷ Veterans having "quality" private insurance, such as Blue Cross/Blue Shield, have identified VA hospitals as an additional source of care only thirteen percent of the time.¹⁶⁸ The veteran who has the income or insurance to go elsewhere apparently does so.

Recent efforts aimed at holding the line on health care expenditures within the VA medical system (part of the efforts to curb the soaring federal deficit), have left the veterans who depend on the system concerned about the availability of care now and in the future.¹⁶⁹ The 1986 Amendments have "whittled down" the group with absolute entitlement to those with service-related injuries or the very poor.¹⁷⁰

Access for the Underinsured, 1 J. HEALTH CARE FOR THE POOR & UNDERSERVED 364, 373 (1991).

162. *Id.*

163. Peter G. Gildschmidt, *Health Services Research and Development: The Veterans Administration Program*, 20 HEALTH SERVICES RES. 789, 794 (1986).

164. John A. Gronvall, *Low Income Veterans in the VA Health Care System*, 6 HEALTH AFFAIRS 167 (1987). Almost 45% of veterans hospitalized in the VA system have no other health insurance coverage, whereas only 7.8% of veterans treated in non-VA hospitals are without insurance. *Id.*

165. *Id.* at 171. These "non-private" types of insurance include medicare, medicaid, or CHAMPUS (Civilian Health and Medical Program of the Uniformed Services), for the military, and CHAMPVA (Civilian Health and Medical Program of the Veterans Administration). The end result is that while 83% of veterans discharged from non-VA hospitals had private health insurance, only 34% of veterans had either private or a combination of private and non-private insurance. *Id.*

166. J. William Hollingsworth, *The Role of Veterans Affairs Hospitals in the Health Care System*, 322 NEW ENG. J. MED. 1851, 1852 (1990).

167. See *supra* notes 135-43 and accompanying text.

168. Gronvall, *supra* note 164, at 172.

169. See Stewart Powell, *Veterans' Care: Condition Critical*, U.S. NEWS & WORLD REP. (June 6, 1986) at 20.

170. See *supra* notes 158-60 and accompanying text. While all veterans within certain

2. The VA Medical System

The VA medical centers "are a vital resource for the organization and delivery of health services to our veterans as well as for the production of much-needed health manpower and making contributions to scientific advances in medicine."¹⁷¹ Presently, the primary connection between the VA and the private health care sector is through its affiliations with medical schools, teaching hospitals, and other institutions that train health care professionals.¹⁷² The result of this close affiliation is that 134 of 172 VA medical centers are affiliated with medical schools and more than half of all practicing U. S. physicians have been at least partially trained in a VA facility.¹⁷³

As a corollary to its affiliations with medical schools, the VA medical system has also actively supported physicians' research endeavors.¹⁷⁴ VA hospitals have given physicians the opportunity to provide clinical health care to VA patients while simultaneously allowing them to participate in teaching and research endeavors.¹⁷⁵ The VA system has actively encouraged this dual activity by providing both opportunities to obtain special research funds and positions that allow significant time for medical research.¹⁷⁶ These activities have resulted in "a significant portion of the nation's investment in medical research (\$212 million in fiscal year 1991) . . . being derived from the VA appropriations."¹⁷⁷ Up to one-third of all American physician investigators have been supported by the VA system.¹⁷⁸

Former VA Secretary Edward J. Derwinski had proposed a complete reorganization of the VA medical system which would re-allocate health care resources to geographic areas where there was

categories of military service were promised free medical care in their old age, now only the poorest are entitled to it. *Id.*

171. C. Alex Alexander, *Physicians in the Department of Veteran Affairs*, 152 ARCH. INTER. MED. 502, 502 (1992). World War II dramatically challenged the capacity of the VA system. The VA System Department of Medicine and Surgery, established in 1946, expanded hospital capacity through the creation of working relationships with American medical schools; see also, John A. Gronvall, *The VA's Affiliation with Academic Medicine: An Emergency Post-War Strategy becomes a Permanent Partnership*, 64 ACAD. MED. 61, 63 (1989).

172. John K. Iglehart, *The Veterans Administration Medical Care System and the Private Sector*, 313 NEW ENG. J. MED. 1552, 1553 (1985).

173. Alexander, *supra* note 171, at 502.

174. See Gronvall, *supra* note 171, at 63.

175. Hollingsworth, *supra* note 166, at 1855.

176. Gronvall, *supra* note 171, at 63-64.

177. Alexander, *supra* note 171, at 502.

178. Gronvall, *supra* note 171, at 63. The VA has been successful in that almost 50% of the medical graduates remain within the VA system as researchers. Another 25% remain in research, but practice within non-VA academic positions. *Id.* at 64.

the greatest need for them.¹⁷⁹ He justified these changes when he stated that the system was "ill-prepared to meet veterans' current and future needs" due to its inappropriate emphasis on inpatient (as opposed to outpatient) care, duplication of services and inability to care for the growing numbers of aging veterans.¹⁸⁰ As part of this proposal, Derwinski recommended that two underutilized VA facilities be opened to other paying patients. Responding to a strong lobbying effort by veterans groups, Congress rejected this proposal.¹⁸¹

Recently, Derwinski resigned from his VA cabinet post to work on President Bush's reelection campaign. It has been charged that he was forced from office by angry veterans groups who fear he would further dilute and streamline VA services into other federal health care programs.¹⁸²

Also, the quality of care within the VA system is allegedly slipping. Many news stories have described overcrowded conditions, increasing suicide rates among patients, and long waiting periods for an available VA hospital bed.¹⁸³ In the spring of 1991, North Chicago VA Medical Center made headlines when it publicly announced that several veteran deaths were the result of "poor care" at its facility.¹⁸⁴ Although the VA system is not necessarily in "dire straits," all agree that the system faces many challenges to maintaining quality medical care, especially as the large number of World War II veterans reach old age.¹⁸⁵

Many consider the VA affiliation with medical schools troubled. Certain commentators complain that the direction of available VA medical care is determined more by the needs of the academic community than of the VA patient population.¹⁸⁶ Others state that the VA system has only benefitted from affiliation with medical schools, and the financial constraints of the federal deficit have been the

179. Cathy Tokarski, *Political Handcuffs Restrain VA Reform*, MOD. HEALTHCARE, April 2, 1990, at 19.

180. *Id.*

181. Eric Schmitt, *Angry Veterans Groups Say They Made Bush Oust Agency's Head*, N.Y. TIMES, Sept. 29, 1992 at A17.

182. *Low Crawl at the White House*, WASH. POST, Sept. 30, 1992, at A22 (Editorial Page).

183. Tokarski, *supra* note 179, at 19.

184. Jonathan Sunshine, *North Chicago and VA Values*, VA PRACTITIONER January, 1992 at 63.

185. Judy Packer, *VA Budget Gets Boost from Gulf War*, MOD. HEALTHCARE, April 22, 1991 at 22.

186. Harry Schwartz, *VA and Medical Schools: A Troubled Marriage?*, 9 VA PRAC. 55, 55 (1992).

prime justification for cuts in available services.¹⁸⁷ Since the medical school connection has been successful in many ways in the past, it is considered unlikely to change in the future.¹⁸⁸ Consequently, the VA patient will continue to be exposed to countless opportunities to participate in medical research with the medical residents and academically involved practitioners.

III. PRISONERS: A CLASSIC "VULNERABLE GROUP"

Prisoners are very similar to VA medical patients in that they are both captive and economically disadvantaged. While confinement by the state makes the prisoner more vulnerable than the VA patient, the underlying causes of their vulnerability are similar. Of the two elements often lacking in vulnerable populations, capacity and autonomy, prisoners and VA patients both experience problems with autonomy rather than capacity.¹⁸⁹

Although rarely used for nontherapeutic research before World War II, American prisoners were extensively used to develop treatments for war-related afflictions of the armed forces during that conflict.¹⁹⁰ After World War II, research continued on prisoners in American prisons. Prisoners participated in projects by pharmaceutical manufacturers for Phase I drug and cosmetic testing,¹⁹¹ in other nonrelated forms of therapeutic research, and in studies related to the causes and effects of incarceration.¹⁹²

Senate hearings in 1973 reviewing research involving prisoners exposed problems surrounding their participation.¹⁹³ These concerns, especially coupled with the abuses exposed in the Nuremberg trials,¹⁹⁴ led Congress to specifically include prisoners in the man-

187. See Hollingsworth, *supra* note 166.

188. Iglehart, *supra* note 172, at 1553.

189. Protection of Human Subjects, 38 Fed. Reg., *supra* note 2, at 31,740. Since veterans are exclusively within the adult population, the issues raised within the vulnerable groups of children, pregnant women and fetuses will be very dissimilar from those of VA medical patients. *Id.*

190. THE NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, RESEARCH INVOLVING PRISONERS: REPORT AND RECOMMENDATIONS 1 (1976) [hereinafter PRISONERS' REPORT].

191. *Id.* Phase I drug testing is a type of research primarily done by the pharmaceutical manufacturers as part of the clinical testing necessary to license new drugs. In these clinical trials, healthy subjects receive successively larger doses of a drug to evaluate its action and safety. *Id.*; see also Barber, *supra* note 12, at 157.

192. PRISONERS' REPORT, *supra* note 190, at 2.

193. *Id.* at 3. The hearings examined the advantages of using prisoners, administrative availability, and concerns about "exploitation, secrecy, danger and the impossibility of obtaining informed consent." *Id.*

194. See, e.g., ANNAS, *supra* note 35, at 104.

date to the National Commission to study and make recommendations concerning their involvement in medical research.¹⁹⁵ A later section will detail the analysis and recommendations made by the National Commission for use of prisoners in medical research.

A. Why Prisoners Are a Vulnerable Population

Prisoners offer a clear example of a captive population that must rely on the government to provide almost all fundamental health and human services. Prisoners are physically captive and look to prison authorities for virtually all of their personal needs. By definition and design, there is an extremely unequal power structure between the inmates and prison officials. Compounding their physical confinement, prisoners are also subject to many attacks on their self-image through deprivation and control.¹⁹⁶ Prisoners live in a situation of social and economic deprivation.¹⁹⁷ These harsh living conditions has led commentators to argue that prisoners are in a situation totally incompatible with the exercise of free choice.¹⁹⁸

There are several ways in which external influences on the prisoner reach a level extreme enough to rob him of his capacity to consent. The two major influences are the inherently threatening or coercive nature of the prison environment and the extremes to which individual prisoners will go to improve their personal situation within the prison.¹⁹⁹ The National Commission did not suggest that overt threats by guards was the typical method for recruiting research participation.²⁰⁰ However, promises of release or sentence reduction as rewards for research participation were considered inherently coercive. Such promises, although positive,

195. Kathleen Schroeder, *A Recommendation to the FDA Concerning Drug Research on Prisoners*, 56 S. CAL. L. REV. 969, 971 (1983). Earlier reports of up to 85% of new drug studies used prisoners as study populations had dropped to a much lower figure by 1980. See also FADEN & BEAUCHAMP, *supra* note 8, at 214-16. The National Commission evaluated the appropriate use of prisoners in research in light of the ethical principles of respect for persons and justice. Congress directed that it determine: (1) whether prisoners bear a fair share of the burdens and receive a fair share of the benefits of research; and (2) whether prisoners are, in the words of the Nuremberg Code, "so situated as to be able to exercise free power of choice"—that is, whether prisoners can give truly voluntary consent to participate in research. PRISONERS' REPORT, *supra* note 190, at 5.

196. PRISONERS' REPORT, *supra* note 190, at 56.

197. *Id.* at 6.

198. LEVINE, *supra* note 3, at 278.

199. Roy Branson, *Philosophical Perspectives on Experimentation with Prisoners*, in THE NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, RESEARCH INVOLVING PRISONERS: APPENDIX TO REPORT AND RECOMMENDATIONS, 1-1 to 1-41 (1976) [hereinafter PRISONERS' REPORT-APPENDIX].

200. See generally PRISONERS' REPORT, *supra* note 190.

were coercive because they implied a threat of extended imprisonment for noncompliant subjects.²⁰¹

When the general conditions in the prison are very poor, the research facilities may provide a living environment significantly better than normal prison conditions.²⁰² When conditions are such that the only way a prisoner can obtain decent living accommodations or basic medical care is as a research participant, that situation is coercive.²⁰³ In this situation, the environment instead of an individual makes offers to alleviate severe economic deprivation coercive.²⁰⁴

One commentator has described prisoners' consent to participate in research as "cheap consent" which mocks the prisoners' right to choose appropriately.²⁰⁵ Manipulation which results in a reduction of the available options could effectively deny a person the ability to make a rational choice. Individual choice has a rational basis only if a variety of alternatives exist. Would the significant number of prisoners who volunteer for research to improve their living conditions or to earn significantly higher incomes participate as freely if their baseline conditions were better?²⁰⁶ Because the ability to make a rational choice is restricted when the range of available options is limited, manipulating available alternatives denies a person of his right to make an autonomous decision.

B. National Commission Recommendations

The National Commission recognized that the ethical principle of respect for persons required that prisoners be given the opportunity to participate as research subjects.²⁰⁷ They concluded, however, that prisons are so inherently coercive that protection from external exploitation was necessary.²⁰⁸

One hurdle to the ethical use of prisoners for research is created by cash payments for participation. The FDA considered cash payments to be a benefit for subjects within the risk-benefit analysis.²⁰⁹

201. ANNAS, *supra* note 35, at 115.

202. *Id.* at 113.

203. LEVINE, *supra* note 3, at 278.

204. FADEN & BEAUCHAMP, *supra* note 8, at 344.

205. Cornel West, *Philosophical Perspective on the Participation of Prisoners in Experimental Research*, in PRISONERS' REPORT APPENDIX, *supra* note 199, 2-1.

206. *Id.*

207. Research Involving Prisoners, *supra* note 149, at 3078.

208. *Id.*

209. Ruth Macklin, *The Paradoxical Case of Payments as Benefit to Research Subjects*, 11 IRB: A REV. OF HUM. SUBJECTS RES. 1 (1989).

Payment for participation creates a paradox for subjects: the higher the monetary payment, the greater the benefit, but also the greater potential that subjects will be unduly influenced to participate.²¹⁰

However, if the research sponsor is permitted to pay significantly less for subjects because they are from a captive population, this gives the sponsor an unfair financial advantage that would encourage the selection of captive populations over more expensive, noncaptive ones.²¹¹ On the other hand, comparable cash payments could result in undue influence within a prison system of lower wages.²¹² Alternate suggestions were made to resolve the injustice.²¹³

Because the National Commission found that prisoners were a vulnerable group, they demanded that enhanced informed consent standards be employed or less vulnerable groups be selected.²¹⁴ The National Commission declared that only certain types of research should involve prisoners,²¹⁵ including therapeutic studies involving traditional medical treatment as well as innovative therapy likely to improve the individual prisoner's health.²¹⁶

Absent stringent controls by a national ethical review body, prisoners were not to be used as subjects for nontherapeutic research.²¹⁷ The National Commission wanted to encourage the involvement of noncaptive populations as research subjects, over captive prison population unless there were "compelling reasons" for the use of the captive prison population.²¹⁸ All categories of research must be reviewed by a local prison IRB with a defined

210. *Id.*

211. *Id.*

212. LEVINE, *supra* note 3, at 282-83.

213. PRISONERS' REPORT, *supra* note 190, at 59. For example, one recommendation to the National Commission was that prisoners be paid the prevailing prison wage, and that the difference between this and rates for outside subjects be placed into a fund to raise prison wages in general. *Id.*

214. *Id.* at 37; *see also* LEVINE, *supra* note 3, at 236.

215. LEVINE, *supra* note 3, at 286. Studies of prisons as institutions and prisoners were encouraged because they are likely to benefit the prisoners as a class of persons and there are no other substitute populations. *Id.*

216. Research Involving Prisoners, *supra* note 149, at 3080. The National Commission did not wish to restrict research likely to personally benefit the subject. *Id.*

217. *Id.* The research must fulfill an important social and scientific need, with compelling reasons for prisoner involvement, prisoner involvement must be "equitable," and require optimal prison conditions allowing a high degree of voluntariness such as adequate living conditions, workable grievance procedures and public scrutiny. *See also* LEVINE, *supra* note 3, at 289. The fact that prisoners are administratively available is *not* a compelling reason to include them in research protocols. *Id.*

218. LEVINE, *supra* note 3, at 290.

membership of much greater diversity than that required for the general population.²¹⁹ In addition, the competence of all investigators must be verified by "the head of the responsible federal department or agency."²²⁰

C. Strict Supervision Versus an Absolute Ban

The underlying conclusion by the National Commission was that the closed and coercive nature of prisons seriously curtailed, but did not totally eliminate, prisoners' capability to provide informed consent.²²¹ That determination led the Commission to recommend an extremely high "compelling need" standard for experimentation which would not directly benefit the individual prisoner or his general class.

Two reports to the National Commission asserted that with certain additional protections, prisoners could voluntarily consent to research participation. One report examined the prisoner's value system and its impact on voluntary choice.²²² Prisoners were seen as comprising diverse groups of divergent identities and goals.²²³ Prisoners volunteered to participate in research either for altruistic or pragmatic reasons or to maximize their comfort by participating in research when benefits outweigh costs.²²⁴ A second report agreed that research on prisoners should be restricted rather than denied.²²⁵ This report acknowledged the difficulty in obtaining consent when such a wide disparity in bargaining power existed, but concluded that consent could be obtained if minimal human rights could be protected and adequately open communication between the inmates and the public could be maintained.²²⁶

219. Research Involving Prisoners, *supra* note 149, at 3081. IRB membership must include prisoners or their advocates, clergy, community representatives, scientists and medical personnel "not associated with the conduct of the research or prison and be of diverse racial and cultural backgrounds." Protection of Human Subjects, *supra* note 102, § 46.304.

220. *Id.*

221. LEVINE, *supra* note 3, at 281.

222. Jackwell Susman, *Two Images of the Prison Influence Structure and Their Meaning for Prisoner Participation in Biomedical and Behavioral Research*, in PRISONERS' REPORT APPENDIX, *supra* note 199, at 4-1 (1976).

223. *Id.* at 4-9. Because different groups of prisoners identify with different groups or people outside of prison, they bring these sub-cultural norms and values with them into prison and its society. *Id.*

224. *Id.* at 4-1, 4-8 to 4-18. See also Schroeder, *supra* note 195, at 977.

225. John Irwin, *An Acceptable Context for Biomedical Research*, in PRISONERS' REPORT APPENDIX, *supra* note 199, at 5-3 to 5-5.

226. *Id.*

D. Prisoner Regulations

In 1978, HHS responded to the National Commission recommendations by publishing final regulations on research using prisoners as subjects. Rather than following the National Commission, which would have permitted non-therapeutic research on prisoners if strict requirements were met, the HHS regulations banned this type of research entirely.²²⁷ Therapeutic research where prisoners might be assigned to control groups also required prior national public notice and approval.²²⁸ The HHS regulations also stated that prison IRB membership must include a prisoner representative, as well as a majority of members having no prison association.²²⁹ In addition, the local prison IRB was to ensure an appropriate risk-benefit analysis, a subject selection program free of arbitrary prison intervention, and avoidance of manipulation or undue influence.²³⁰

Reacting to concerns expressed by prisoners in legal actions, the FDA stayed the effective date of its regulations and published new proposed regulations in December 1981.²³¹ The final FDA regulations did not completely ban nontherapeutic research. Rather, the FDA adopted the prohibitive "compelling need to use prisoners" standard recommended by the National Commission.²³² The FDA's revised regulations stated that the agency had previously omitted the "compelling need" standard because it was considered an unreachable goal.²³³

227. *Id.* § 46.306.

228. *Id.* § 46.306a. Research involving control groups containing prisoners, or research on conditions particularly affecting prisoners may proceed "only after the Secretary has consulted with appropriate experts . . . and published notice, in the *Federal Register*, of his intent to approve such research." *Id.*

229. Protection of Human Subjects, *supra* note 102, § 46.304.

230. *Id.* § 46.305a.

231. LEVINE, *supra* note 3, at 294. In response to the initial HHS prisoner regulations of 1980, which banned non-therapeutic research, Jackson State prisoners filed a lawsuit challenging these regulations as violative of their constitutional right to participate in non-therapeutic Phase I clinical trials. Protection of Human Subjects; Prisoners Used as Subjects in Research, 45 Fed. Reg. 36,386 (1980). *Fante and The Upjohn Co. v. Department of Health and Human Services*, Civ. Action No. 80-72778, U.S. Dist. Ct., E.D. Mich., 1980. See also LEVINE, *supra* note 3, at 294. Other prisoners, who felt that their participation in non-therapeutic research was involuntary and therefore unconstitutional, due to poor prison conditions, were denied relief in an unrelated action. In denying relief, the court found, indirectly, that prison conditions were neither inherently coercive nor inherently incompatible with autonomous research participation decisions. *Bailey v. Lally*, 481 F.Supp. 203 (D. Md. 1979).

232. *Id.* at 295. The FDA felt that no research would be found to meet this standard, so the category was still effectively banned. LEVINE, *supra* note 3, at 295.

233. Protection of Human Subjects, 46 Fed.Reg. 61,666, 61,668 (1981). FDA concluded that in view of the National Commission's finding that prisons are inherently coercive and of

Post-regulatory analysis has questioned the need for the FDA and HHS to impose a defacto ban on nontherapeutic research within prisons.²³⁴ The goals of the National Commission to assure adequate standards of justice and voluntariness could also be met with additional safeguards, that still allow the prisoners the right to choose for themselves.²³⁵

The National Commission's primary concern was that the prisoners would choose to participate in research for improper or invalid reasons.²³⁶ Certain commentators have taken the extreme position that involvement for any materialistic reasons is unethical because the nature of the commodity at risk involved is one's own health and body rather than something less essential.²³⁷ More moderate commentators have stated that weighing the potential risks of research participation against the benefit of financial gain is acceptable within reasonable limits.²³⁸

The controversy over the choice between an absolute ban or restricted use of certain categories of certain categories of experimentation is directly related to the degree of perceived inability to obtain appropriate consent from prisoners. Those who perceive no external protection strong enough to insure autonomous consent favor an absolute ban. Others, while acknowledging the possibility of external control, still recommend its prohibition due to ease of administration.

IV. SHOULD VA MEDICAL PATIENTS BY CONSIDERED A VULNERABLE GROUP?

The VA medical patients should be identified as a vulnerable population in order to best protect their capacity to give informed consent in medical research settings. Examining the VA patient's ability to consent under the contract law model highlights points of heightened vulnerability.²³⁹

the lack of evidence that other groups of potential research subjects could not be found, the need to protect prisoners outweighed any need to use prisoners that had yet been presented to FDA. Thus, it appeared to the agency that sponsors of research could never establish a compelling need to use prisoners. *Id.*

234. *See generally* Schroeder, *supra* note 195.

235. *Id.* at 999-1000.

236. ANNAS, *supra* note 35, at 106.

237. Marx W. Wartofsky, *On Doing It For Money, in* PRISONERS' REPORT APPENDIX, *supra* note 199. When a subject puts his personal health at risk reasons other than freely given such as in exchange for money or material reward, "the act is akin to prostitution." *See also* PRISONERS' REPORT, *supra* note 190, at 53.

238. *See generally* Irwin, *supra* note 225.

239. *See supra* notes 58-79 and accompanying text.

Lack of appropriate capacity to consent was one of the two primary concerns identified by those evaluating vulnerable groups.²⁴⁰ Capacity to consent is a baseline determination required for measuring whether a particular group in question possesses the ability to consent to research participation. VA medical patients, like prisoners, possess the capacity to consent in the sense that they are legally competent adults. Nevertheless, the prisoners' inherent capacity to consent did not prevent their classification by the National Commission as vulnerable, nor should it for VA patients.

Autonomy is the second primary concern identified by those studying vulnerable populations. When a class *is* considered competent to consent, but there is a strong suspicion that individual actions taken by members of this class are *not* autonomous, then that class is also considered vulnerable.²⁴¹ The contract model has previously shown the more power is divided unequally, as in a subject/investigator relationship, the greater the threat autonomy will be lost in negotiations for consent. While an investigator's appeal to participate in medical research will be merely persuasive for some patients, for others, this influence will manipulate or coerce in ways that effectively deny autonomous informed consent. These subjective interpretations of the external influences must be considered when there is a suspicion that individuals within a class of competent people are not freely choosing research participation. These influences have been previously identified and will now be evaluated as they effect VA patients.²⁴²

Coercion has been found incompatible with effective informed consent.²⁴³ Coercion goes beyond overt threats of harm. For example, in the prison context promises of early release or sentence reduction in exchange for research participation constitute coercion. There is no indication that the VA patients experience any overt coercive threats. VA patients, like prisoners, are subject to more subtle coercive influences.

The potential for unacceptable methods of manipulating of the VA patient to participate in medical research can take many forms. The question of when persuasion rises to manipulation or coercion can best be answered from the patient's subjective perspective.

When a patient's fears are not are not likely to be realized, an objective reasonable person standard might fail to consider certain

240. See Kjervik, *supra* note 58, at 194.

241. LEVINE, *supra* note 3, at 97.

242. See *supra* notes 76-92 and accompanying text.

243. See *supra* note 176.

incentives an infringement on effective consent. Because it is the individual's subjective interpretation of the situation that may serve to deny him the right to freely choose to participate in research, any objective standards used in groups particularly vulnerable should be reformulated to account for this greater subjective vulnerability.

1. Captive

The VA patient clearly belongs in the category of captive populations. The typical VA patient, because of his legislated entitlement to health care, is uniquely dependent upon the VA medical system to meet his medical needs if he cannot afford alternative health care coverage.²⁴⁴ This type of captivity is similar to that of prisoners because his only choice is to accept that offered by the government (through the VA hospital or prison infirmary, respectively) or to forego treatment altogether.²⁴⁵

The VA patient also shares with the prisoner a second, more unusual dimension of captivity. The VA system of medical facilities is structured so that patients may normally obtain care only from the nearest VA hospital. As a result, the dissatisfied VA patient cannot transfer to another VA facility. Moreover, this patient, who is also typically poor, cannot easily afford to transfer to other indigent care facilities because of the large copayments and deductibles required for other public assisted health coverage.²⁴⁶ Thus, the VA patient is both restrained economically to use the VA hospital and also geographically restrained to a particular medical facility.²⁴⁷ Although technically not a prisoner, the VA patient, as a result of his circumstances, is likely to feel that he *must* seek medical care at a particular VA medical facility or face the possibility of no medical attention at all.

Although most people are dependent upon others, captive populations' dependence upon others for fundamental personal services, such as medical care, may make them more susceptible to control by their caretakers.²⁴⁸ Because the VA patient is captive within the system, he is more dependent on VA medical personnel than a pa-

244. See *supra* notes 135-137 and accompanying text.

245. See *supra* notes 196-201 and accompanying text.

246. See *supra* notes 167-170 and accompanying text. This type of environmental restriction is not shared by other indigents looking for state-assisted medical care because typically there is a greater number of medical centers providing this care within a geographic location. VA patients may also be eligible for other state-assisted care, but copayments and deductibles make it prohibitively expensive.

247. Reatig, *supra* note 142, at 182.

248. See *supra* notes 137-40 and accompanying text.

tient of a private caregiver and consequently more likely to react passively to research participation requests. This greater dependency potentially creates an environment fostering unintentional manipulation, by role constraints, in which an investigator's expectations of VA patient participation inadvertently compel his compliance.

The VA patient cannot give effective informed consent if he feels powerless and trapped within the VA medical system, and these feelings lead him passively to allow others to dictate or control his personal decisions.²⁴⁹ The VA patient is particularly susceptible because he is a captive within the VA system and must be protected against passive manipulation in this dependent situation.

2. Economically Disadvantaged

The typical VA medical patient is relatively impoverished compared to the general public. Unless the veteran has a service-related injury, he cannot use the VA medical system if his personal income rises above a legislatively mandated level.²⁵⁰ Even the geriatric veteran can no longer use the VA system if he has moderate personal wealth.²⁵¹ For these reasons, the population using the VA medical system can easily be characterized as economically disadvantaged.²⁵² In addition to this relative poverty leading to excessively passive behavior by the VA patient, the economically disadvantaged VA patient may be unusually affected in other ways.

When a subject is impoverished, there is a greater risk that the financial compensation offered to join a research protocol will unduly manipulate this participation.²⁵³ The poorer the subject, the greater the potential that "cash payments" for research participation will excessively influence or manipulate his decision. While it is recognized "that *some* inducement is necessary to prompt a sufficient number of people to volunteer to serve as research subjects,"²⁵⁴ beyond a certain point this inducement becomes undue. "Inducements that would ordinarily be acceptable may become undue influences if the subject is especially vulnerable."²⁵⁵

The poor VA patient is particularly susceptible to undue inducement.

249. See *supra* notes 88-91 and accompanying text.

250. See *supra* notes 107-110 and accompanying text.

251. *Id.*

252. See generally Gronvall, *supra* note 164.

253. LEVINE, *supra* note 3, at 82.

254. Macklin, *supra* note 71, at 1.

255. BELMONT REPORT, *supra* note 1, at 4.

ments of cash payments to entice his research participation as is the prisoner. Since most VA patients are poor, any significant amount of money has the potential to be so desirable that refusal to participate is not a realistic alternative. Lacking available alternatives for affordable medical care, VA patient's consent also can be characterized as "cheap consent" which denies the VA patient his inherent right to freely choose research participation.

3. Threats and Manipulation

When patients dependent upon an outside organization feel threatened, they are more likely to be manipulated. The environment in which the VA patient exists threatens his continued medical care in several ways.

The entitlement to medical care provided to veterans was significantly restricted in the Veterans' Health Care Amendments of 1986.²⁵⁶ Also, commentators note a correlation between the lessening legitimacy of veterans' claims to separate medical care and the lack of any major war within the last several decades.²⁵⁷ As the personal memories of veterans' sacrifices in World War I and II decreases, so does the perceived validity of veteran's claim of entitlement to special separate health care coverage.²⁵⁸ The veteran's unique entitlement to health care has also diminished as more Americans today support the idea of universal health insurance for all citizens, which would encompass the VA system, Medicaid, and Medicare.²⁵⁹

The fear that these growing sentiments has raised among veterans is exemplified in the pressure that veterans groups reportedly used to force the ouster of Veterans Affairs Secretary Edward J. Derwinski.²⁶⁰ Although Derwinski had been very successful at increasing the VA budget in troubled economic times,²⁶¹ he "ran afoul of the large veterans groups by pressing for a pilot program that would have opened a VA hospital in Virginia and another one in Alabama to poor, rural residents who lacked adequate medical care."²⁶² "[V]eterans groups saw or portrayed the experiment as a

256. See *supra* notes 159-162 and accompanying text.

257. Harry Schwartz, *Running the Resource Race*, 9 VA PRACT. 53 (1992).

258. *Id.* at 54.

259. *Id.*

260. Schmitt, *supra* note 181.

261. *Id.*

262. Ann Devry & Bill McAllister, *Derwinski Quits Bush's Cabinet; Move to Campaign Follows Calls by Veterans Groups for Ouster*, WASH. POST, Sept. 27, 1992, at A1, A23. In February [1992], less than five hours after the Senate voted 91 to 3 to block the pilot program,

first step toward the possible merger of the veterans' and civilian health care systems, and the secretary was forced to back down."²⁶³

The VA patient may be justifiably concerned about his ability to continue receiving quality health care when he reads published reports about services available within the VA system. News media coverage of veteran deaths and poor quality care abound.²⁶⁴ The quality of health care in the VA system is considered by many to be questionable and steadily deteriorating.²⁶⁵ Indeed, many veterans consider the quality and availability of their future care extremely uncertain.²⁶⁶ Their care, although an entitlement, may well be vanishing into a mire of second class service and denied benefits.

Given the current status of the VA system and the necessity that an individual patient use only the area VA hospital, it is easy to understand individual VA patients fearing that refusal to participate in medical research may jeopardize their status within the VA medical system. Effective informed consent will be threatened if the VA patient, for whatever reason, translates concerns for the future availability of his medical care into a fear that this future care will be further jeopardized if he fails to cooperate with a request to participate in research. This leads to "cheap consent" which mocks the VA patient's right to appropriately choose research participation just as it did with prisoners.²⁶⁷

The key question in the process of protecting VA patients is when does persuasion to participate in medical research become manipulation or coercion which effectively denies informed consent for the VA patient. VA patients must be protected in whatever way necessary to maintain substantial autonomy in making the decision to participate in medical research. It is imperative that any objective, reasonable person standard used to answer this question be modified in ways that strengthen the informed consent process. The VA patient must be protected against the dramatically greater likelihood of overt or passive manipulation which are inherent in unequal or dependent relationships such as the one in which the VA patient finds himself. Although the class of VA patients is considered competent to consent to participate in medical research, how-

Mr. Derwinski announced that he was withdrawing the plan because of veteran opposition. Schmitt, *supra* note 181, at A17.

263. See *supra* note 182 and accompanying text.

264. See *supra* notes 185-87 and accompanying text.

265. See *supra* notes 128-30 and accompanying text.

266. Powell, *supra* note 169, at 22.

267. See *supra* note 207 and accompanying text.

ever, individually there is a great deal of suspicion that particular choices are not made autonomously, therefore, this class should be considered vulnerable and afforded the appropriate additional protection.

E. The VA System Has Failed to Protect Patients Because of its Failure to Identify Them as a Vulnerable Population.

The VA medical system manages itself in a manner that implies its recognition of vulnerable population status, but it has never officially labeled the VA patient as vulnerable. Because this population can be shown to be vulnerable, it is essential that it be labeled as such immediately in order to properly evaluate its appropriate use as a research subject body.

The VA system recognized a greater than normal need for protection within its patient population when it applied additional regulations for research on VA patients. These stricter regulations include prohibition of expedited review of research protocols by IRBs, prohibition of short form or waiver of certain consent requirements, and cash payments in all but limited circumstances.²⁶⁸ This stricter requirement that the VA system has imposed upon itself reveals its concern that informed consent is threatened to the extent that the local IRB analysis is insufficient to protect its patients against undue external influence.

These additional protections, however, pale next those given to other vulnerable groups. For example, the use of prisoners in research, has been restricted to a compelling need standard for certain categories of research that virtually bans all nontherapeutic research and requires prior national public notice and approval for therapeutic research using subject control groups. Prison IRB membership has been redefined to include more outsiders free from prison supervision and heightened scrutiny to ensure a selection program free of arbitrary prison intervention.

Informed consent has developed into a complex, rigid set of regulations with the local IRB acting as the watchdog of the subjects' interests. But the IRBs suffer from a lack of organized communication between units. Adequate protection provided at one center may not be consistently duplicated at another without express identification of this group as "vulnerable." VA patients will be better protected if the VA system recognizes their status as a vulnerable

268. See *supra* notes 123-30 and accompanying text.

group and modifies the objective standards for their inclusion in research appropriately.

Once the VA patients are identified as a vulnerable population, ethical considerations require an evaluation of its equitable use as a research subject body. The National Commission recommended that groups particularly vulnerable to external control be avoided as sources for research subjects when other less vulnerable groups can be used and specific justification of their inclusion is required.²⁶⁹ For example, when the prisoner population was evaluated by the National Commission for acceptable conditions under which prisoners could safely participate in research, only therapeutic research was permitted. This justification for therapeutic research developed because participation in the research offered the potential for personal gain.²⁷⁰ Whether an absolute ban on the use of VA patients is warranted has to be answered, but only following research undertaken to assess the nature and extent of the inherent vulnerability of this population. Although VA patients are not vulnerable enough to justify imposing a research ban, the strength of the external influences that threaten to deny their autonomous right to freely choose research participation must not be ignored.

In general, the additional burdens of research participation ethically can be offset if the benefits of improved medical technology are also offered to the VA patient. There is no data that indicates VA patients are denied the resulting benefits of research conducted upon them. Patients who participate in therapeutic research potentially may receive benefits from new forms of medical therapy. But if the financial constraints and service cutbacks which currently plague the VA medical system result in fewer of these benefits reaching the VA patient, then the additional burdens of using a group more vulnerable will not be adequately offset and the ethical principle of comparative justice will be violated.

It is obvious that the VA affiliation with medical schools has been very profitable for the VA system and the medical community as a whole.²⁷¹ This affiliation would suffer seriously if the opportunities for research investigation were eliminated within the VA population. Although these benefits to medical education cannot be ignored, the special needs of the VA patient also must be addressed.

269. Lebacqz, *supra* note 147, at 3; *see also supra* notes 241-249 and accompanying text.

270. *See supra* notes 25-35 and accompanying text.

271. Schwartz, *supra* note 186, at 55.

CONCLUSION

The VA medical patient must be officially recognized by the VA medical system as a vulnerable group. Once this step is taken, the objective standard used to determine the presence of adequate informed consent must be strengthened for the VA patient in order to provide adequate protection that his subjective concerns will not create a situation which coerces or manipulates his decision to participate in medical research. The "just" use of VA patients in research must be evaluated and affiliations with academic medicine modified, if necessary, to protect the VA patient first and foremost above all other interests or concerns. Most of the people using the services have no viable alternatives to adequate medical care. The poverty of the patients, when combined with the entitlement to free medical care without costly co-payments and deductibles, make the services provided by the VA system difficult to refuse. In addition, the typical VA medical patient is also the captive of the VA hospital in his region. As a result, the VA patient may perceive himself to be without options with respect to the system providing his care.

Many have questioned why the VA patient population should be protected when similar populations are not. While several groups may show traits similar to being captive or impoverished, few do to the same extent as the VA patient. While other groups, such as pharmaceutical company employees, and medical or psychology students are in restrictive situations similar to the VA patient, they usually are not as impoverished to the extent Veteran's eligible for VA care are impoverished. Other groups, such as the welfare patient, the Medicaid and Medicare patient may be equally impoverished, but they can usually obtain some type of medical care from more than one facility within any given geographic location. However, nothing should preclude the knowledge gained from research on the VA population from being extended to resolve similar problems affecting the other groups mentioned.

