

# NOTE

## HEW PROPOSED POLICY ON THE PROTECTION OF HUMAN SUBJECTS: EXPERIMENTATION AND THE INSTITUTIONALIZED MENTALLY DISABLED

### I. INTRODUCTION

Our society is committed to scientific and medical progress.<sup>1</sup> One manifestation of that commitment is the governmental allocation of fiscal resources to research. In 1937, the United States Government began a medical research program which expanded dramatically after World War II to become a billion dollar enterprise by 1968.<sup>2</sup> Despite cutbacks during the Nixon and Ford Administrations, research, aided by grants from the Department of Health, Education, and Welfare (HEW),<sup>3</sup> continues to proliferate.<sup>4</sup>

With federal interest and aid has come a measure of federal control. As amended in 1967, section 355(i) of the Federal Food, Drug and Cosmetic Act now requires that before a drug "intended solely for investigational use" can be dispensed, an investigator must obtain informed consent from all subjects.<sup>5</sup> The reach of the section is limited to

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1. See Jonas, *Philosophical Reflections on Experimenting with Human Subjects*, in EXPERIMENTATION WITH HUMAN SUBJECTS 1, 13 (P. Freund ed. 1969) [hereinafter cited as Freund]. The statement has been referred to as a "truism," Jaffe, *Law as a System of Control*, in Freund 197, and an "essential," Ladimer, *Ethical and Legal Aspects of Medical Research on Human Beings*, in CLINICAL INVESTIGATION IN MEDICINE 179 (I. Ladimer & R. Newman eds. 1963) [hereinafter cited as Ladimer & Newman].

2. See Curran, *Governmental Regulation of the Use of Human Subjects in Medical Research: The Approach of Two Federal Agencies*, in Freund 402.

3. The National Institutes of Health (NIH) branch of the Department of Health, Education and Welfare (HEW) grants financial support to proposals for research that it perceives to be of scientific significance and of potential benefit to mankind. Scientists compete for NIH funding, the provision of which is said to be based on the merits of the proposal itself rather than on a system of support to favored institutions. *Id.* at 432.

4. See, e.g., S. REP. No. 381, 93d Cong., 1st Sess. (1974) (history and development of NIH, see note 3 *supra*, and National Institute of Mental Health training programs).

5. 21 U.S.C. § 355(i) (1970), amending 21 U.S.C. § 355(i) (1964).

nontherapeutic experimentation,<sup>6</sup> however, and its jurisdictional base is dependent upon the proposed introduction of the drug into interstate commerce.<sup>7</sup>

A second area of federal review is based on the power of the Secretary of HEW to impose conditions upon the dispensing of research grants.<sup>8</sup> In 1966, the Surgeon General<sup>9</sup> announced that the Public Health Service would review research grants for compliance with three principles: consideration of the rights and welfare of subjects; acquisition by appropriate methods of informed consent; and determination of the benefits and risks of the investigation.<sup>10</sup> These three tenets have remained at the heart of all HEW regulation including HEW's current, extensive rule-making activity.<sup>11</sup>

This Note will explore the underlying bases for federal interest in the area of experimentation on human subjects, including the nature of experimentation, abuses of investigative processes, and prior efforts at regulation. The recently promulgated HEW rules and regulations on the protection of human subjects will be examined in detail, with

6. See notes 31-32 *infra* and accompanying text.

7. See Morse, *Legal Implications of Clinical Investigations*, 20 VAND. L. REV. 747 (1967); Comment, *Non-therapeutic Medical Research Involving Human Subjects*, 24 SYRACUSE L. REV. 1067, 1080 (1973).

8. 5 U.S.C. § 301 (1970) provides: "The head of an Executive department . . . may prescribe regulations for the government of his department, and the distribution and performance of its business . . ."

9. The Surgeon General is the chief medical officer of the Public Health Service.

10. SENATE COMM. ON LABOR AND PUBLIC WELFARE, 94TH CONG., 1ST SESS., FEDERAL REGULATION OF HUMAN EXPERIMENTATION 14 (Comm. Print 1975), *citing* Pub. Health Serv., Policy and Procedure Order No. 129 (Feb. 8, 1966), *quoted in* Curran, *supra* note 2, at 437. The Surgeon General's policy was based on a 1965 resolution adopted by the National Advisory Health Council. The resolution in turn had been based on recommendations made by an ad hoc committee which had been studying ethical problems underlying the grant program since 1963. Curran, *supra* note 2, at 437.

For a history of Public Health Service policy, see Confrey, *PHS Grant-Supported Research with Human Subjects*, 83 PUB. HEALTH REP. 127 (1968). See also Curran, *supra* note 2; Marston, *The Background of the National Institutes of Health (NIH) Position on Ethical Problems of Clinical Studies*, 23 FERTILITY & STERILITY 596 (1972); Ratnoff, *Who Shall Decide When Doctors Disagree? A Review of the Legal Development of Informed Consent and the Implications of Proposed Lay Review of Human Experimentation*, 25 CASE W. RES. L. REV. 472, 503 & nn.189-92 (1975); Comment, *supra* note 7, at 1081.

11. Beginning in 1971, HEW made public the principles under which it would approve and fund research activities. U.S. DEPT. OF HEALTH, EDUC. & WELFARE, INSTITUTIONAL GUIDE TO DHEW POLICY ON PROTECTION OF HUMAN SUBJECTS (1971) [hereinafter cited as INSTITUTIONAL GUIDE]. These principles were expanded and codified by regulations promulgated in 1975. 45 C.F.R. §§ 46.101-301 (1975).

particular emphasis on control of experimentation affecting the mentally disabled. These rules are an important reflection of present federal policy and will have a significant impact on many research institutions.

## II. THE NATURE OF EXPERIMENTATION

Scientific knowledge may be advanced either by description or experimentation.<sup>12</sup> In the medical sciences, progress is best achieved by the performance of controlled experiments on or with<sup>13</sup> human subjects.<sup>14</sup> Commentators view the necessity for scientific progress ambivalently. On the one hand, experimentation has been called "essential for the welfare of the race;"<sup>15</sup> on the other hand, progress has been viewed as "essentially melioristic" and as such, "in a sense gratuitous."<sup>16</sup> It is agreed, however, that the "good of society"<sup>17</sup> does not empower scien-

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12. Ivy, *The History and Ethics of the Use of Human Subjects in Medical Experimentation*, in Ladimer & Newman 39, 40. Hippocrates (460-370 B.C.), said to have been the founder of descriptive medicine, observed and wrote in detail on human functioning. Galen (131-201 A.D.) may have founded experimental medicine. After the Dark Ages, experimentation was revived by Vesalius (1514-1564 A.D.). The apex of early experimentation came with Harvey's discovery of the circulation of the blood. *Id.*

The "essence" of experimentation is the deliberate application of "certain chosen procedures for the purpose of measuring their effects." Cochran, *Research Techniques in the Study of Human Beings*, in Ladimer & Newman 403, 405. The typical experimental plan consists of the following:

- (a) the construction of two (or more) closely similar groups of patients observed at the same time and differing in their treatment; (b) the construction of these groups by some process of random allocation; and (c) the withholding of a form of treatment from one or other of these groups.

Hill, *Medical Ethics and Controlled Trials*, in Ladimer & Newman 370, 370 (emphasis original). See generally K. COX, PLANNING CLINICAL EXPERIMENTS (1968).

13. The choice of the preposition "on" or "with" was seen by Margaret Mead as having more than an abstract significance. Mead, *Research with Human Beings: A Model Derived from Anthropological Field Practice*, in Freund 152, 164-65. Mead objected to the concept of experimentation on human subjects, arguing that it conjures up the vision of the passive human guinea pig. Experimentation, rather, should be with human subjects as a "truly cooperative enterprise" for the benefit of mankind and also for the enjoyment of participation. Thus, according to Mead, research can be a joint venture which benefits all parties. *Id.*

14. See Ivy, *supra* note 12, at 39. Ebersold, *The University of Cincinnati Whole-Body Radiation Study: For Whose Benefit?*, 15 ATOMIC ENERGY L.J. 155, 158 (1973) comments on the proper staging of experiments beginning with studies on laboratory animals and working through three stages of human experimentation: assessing possible toxicity, determining effectiveness, and comparing a new treatment to those in existence.

15. Beecher, *Experimentation in Man*, in Ladimer & Newman 2, 7.

16. Jonas, *supra* note 1, at 14.

17. The original debate was in large part prompted and influenced by the abhorrence felt by scientists upon learning of atrocities performed by Nazi scientists under

tists to select society's "martyrs."<sup>18</sup>

### A. *Definition and Classification*

The term "experimentation" can be used in many ways. In modern medical thinking, every doctor-patient relationship gives rise to experimentation.<sup>19</sup> Regardless of the therapy administered, to some extent the response of each patient will be unique.<sup>20</sup> Even refraining from treatment can be experimentation.<sup>21</sup> In the nontherapeutic area, conducting medical and psychological tests for the training of students has also been classified as experimentation.<sup>22</sup>

The traditional judicial definition of experimentation, which until recently equated the term "experimentation" with departure from the bounds of accepted medical practice,<sup>23</sup> or with simple quackery,<sup>24</sup> repre-

the guise of legitimate medical experimentation for the furtherance of the war effort and of Nazi theories of German society. See Cowan, *Human Experimentation: The Review Process in Practice*, 25 CASE W. RES. L. REV. 533, 533-34 (1975); Katz, *The Education of the Physician-Investigator*, in Freund 293, 295. Today, thirty years after the Nuremberg trials, scientists are still loath to postulate their aims in terms of "the good of society." For example, Calabresi, *Reflections on Medical Experimentation in Humans*, in Freund 178, 184, expressed the dominant goal as the prevention of both disease and early mortality of future lives. See also Jonas, *supra* note 1, at 13.

18. Beecher, *supra* note 15, at 7. Several commentators express concern over the rights of the individual as contrasted with the demands of society. While some give absolute priority to the individual, most attempt to balance the conflicting claims. See Calabresi, *supra* note 17, at 180; Jonas, *supra* note 1, at 7. See also Jaffe, *supra* note 1, at 197 (questioning this thesis). Furthermore, they point out that even if society's requirements are more compelling, scientists may be incapable either of ascertaining the precise nature of those requirements or of persuading others that they have done so. See Kaplan, *Experimentation—An Articulation of a New Myth*, 46 NEB. L. REV. 87, 101 (1967). See also Mead, *supra* note 13, at 160 (analyzing the issue as a question of power); Note, *Fetal Experimentation: Moral, Legal, and Medical Implications*, 26 STAN. L. REV. 1191, 1205 (1974) (balancing moral repugnance and social productivity).

19. See Cady, *Forensic Medicine*, 6 ANNALS OF WESTERN MEDICINE & SURGERY 164 (1952), reprinted as *Medical Malpractice: What about Experimentation?*, in Ladimer & Newman 170, 176; Freund, *Introduction*, 98 DAEDALUS viii (1969) (introducing Symposium: Ethical Aspects of Experimentation with Human Subjects); Ivy, *supra* note 12, at 39; Kaplan, *supra* note 18.

20. Ivy, *supra* note 12, at 39.

21. The clearest example of this phenomenon is the experimental control who may be given a placebo or literally no treatment at all in lieu of an experimental drug. See note 14 *supra*; Note, *Experimentation on Human Beings*, 20 STAN. L. REV. 99, 100 (1967).

22. Note, *supra* note 21, at 100.

23. Compare *Langford v. Kosterlitz*, 107 Cal. App. 175, 290 P. 80 (1930) (departure from established methods of treatment condemned as experimentation), with Fort-

sents one definitional extreme. While courts today approach the subject with increasing sophistication,<sup>25</sup> all reported cases have dealt with "experimentation" by analogy to medical malpractice,<sup>26</sup> or by a strict liability standard imposed under the "physician's peril" cases.<sup>27</sup> Clearly, a legal definition of experimentation is needed.

Experiments have been classified by any of several variables. The subject's role may be seen as a continuum moving from passive to active;<sup>28</sup> the knowledge sought may be basic or applied science;<sup>29</sup> the objective of the research may be therapeutic and of immediate value to the patient-subject,<sup>30</sup> or nontherapeutic.<sup>31</sup> Nontherapeutic research may be further divided into experiments that are conducted to benefit future patients afflicted with the patient-subject's ailment and those that

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ner v. Koch, 272 Mich. 273, 261 N.W. 762 (1935) (experimentation approved so long as procedures did not represent radical variance from accepted methods).

24. See, e.g., *Kershaw v. Tilbury*, 214 Cal. 679, 8 P.2d 109 (1932); *Ladimer*, *supra* note 1, at 186; *Ratnoff & Smith, Human Laboratory Animals: Martyrs for Medicine*, 36 *FORDHAM L. REV.* 673, 684 (1968).

25. See, e.g., *Kaimowitz v. Michigan Dep't of Mental Health*, Civil No. 73-19434-AW (Cir. Ct., Wayne County, Mich. July 10, 1973), reprinted in A. BROOKS, *LAW, PSYCHIATRY AND THE MENTAL HEALTH SYSTEM* 902, 914, 916 (1974) (discussion of therapeutic experimentation on involuntarily detained mental patient); *In re Weberlist*, 79 Misc. 2d 753, — N.Y.S.2d — (Sup. Ct. 1974) (discussion of experimentation in the context of court-authorized medical intervention).

26. See, e.g., *Karp v. Cooley*, 493 F.2d 408, 423-24 (5th Cir. 1974) (in context of therapeutic experimentation action "must be measured by traditional malpractice evidentiary standards"); see text accompanying notes 92-103 *infra*.

27. The most recent case to use language reminiscent of "physician's peril" was *Fortner v. Koch*, 272 Mich. 273, 282, 261 N.W. 762, 765 (1935).

28. *Beecher*, *supra* note 15, at 18.

29. *Id.*

30. *Id.*; Note, *supra* note 21, at 101.

31. *Beecher, Ethics and Clinical Research*, 274 *NEW ENG. J. MEDICINE* 1354, 1354 (1966); Note, *supra* note 21, at 101. See also *Ratnoff*, *supra* note 10, at 480-81. *Ratnoff* suggested three classifications: (1) "the individual therapeutic experiment" administered to the "critically ill" patient; (2) the experiment in which "new or revised therapy is administered or . . . withheld" from the "less critically ill patient;" and (3) the "manipulative" experiment. A value judgment can be applied to this latter class to subdivide it further into those experiments that are expected to serve humanity, and those that merely seem to satisfy "academic curiosity." *Id.* *Ratnoff & Smith*, *supra* note 24, at 677, suggested that the investigator ask whether the investigation was based on a quest for answers "not honestly needed." This distinction may in fact be too subjective to be useful in the categorization of experiments. Its origin, however, was in the response of the medical community to the Nazi war crimes. By any civilized standard, the need for knowing any of the information derived from the activities described in note 67 *infra* would be at best criminal. The standard may be workable, however, in the context of community and peer review in a manner analogous to the operation of the "reasonable man standard" in the jury trial.

are performed simply to increase the store of scientific knowledge.<sup>32</sup> At some point an experimental procedure becomes accepted medical practice, generally when espoused by the professional community.<sup>33</sup> Significantly, a procedure's acceptance occurs before all of the long-range consequences of the therapy are known. This process illustrates the problems encountered in defining experimentation.

### B. *The Concept of Risk*

While some experiments produce no benefit to the subject, every experiment involves some degree of "risk" to him.<sup>34</sup> Just as no adequate legal definition of "experiment" has evolved, no legal definition of "risk" in the context of medical experimentation has been proposed. The common but unarticulated conception of risk in experimentation focuses upon the possibility of the subject's exposure to physical or psychological harm.<sup>35</sup> A finding of risk thus depends upon how attenuated a possibility of or how slight a harm one perceives in an experimental situation. No attempt has been made to quantify risk or to set legal limits on permissible risk.<sup>36</sup> Factors such as the "intrusiveness"<sup>37</sup> of an

32. See Beecher, *supra* note 31, at 1354; Note, *supra* note 21, at 101.

33. See note 113 *infra*.

34. See M. PAPPWORTH, HUMAN GUINEA PIGS 12, 19 (1967); Addison, *The Legal and Ethical Considerations of Clinical Research*, 40 MEDICO-LEGAL J. 144, 146 (1972); Note, *Medical Experiment Insurance*, 70 COLUM. L. REV. 965, 965 (1970).

35. Commentators use the term "risk" without defining it. See M. PAPPWORTH, *supra* note 34; Addison, *The Legal and Ethical Considerations of Clinical Research*, 40 MEDICO-LEGAL J. 144 (1972); Ratnoff, *supra* note 10; Ratnoff & Smith, *supra* note 24.

Compare the concept of risk in tort law, as set out in RESTATEMENT (SECOND) OF TORTS 282, comment g, at 11 (1965):

The word "risk" standing by itself denotes a chance of harm. In so far as risk is of importance in determining the existence of negligence, it is a chance of harm to others which the actor should recognize at the time of his action or inaction.

See W. PROSSER, HANDBOOK OF THE LAW OF TORTS 146 (4th ed. 1971).

36. *But cf.* RESTATEMENT (SECOND) OF TORTS § 293, listing "Factors Considered in Determining Magnitude of Risk" in assessing negligence:

- (a) the social value which the law attaches to the interests which are imperiled;
- (b) the extent of the chance that the actor's conduct will cause an invasion of any interest of the other or of one of a class of which the other is a member;
- (c) the extent of the harm likely to be caused to the interests imperiled;
- (d) the number of persons whose interests are likely to be invaded if the risk takes effect in harm.

It is important to note that the *Restatement* rules are called into operation only after the allegedly negligent acts have occurred, while the assessment of risk in experimenta-

experimental technique or the "coerciveness"<sup>38</sup> with which it is administered could be used to measure risk.<sup>39</sup> The magnitude of the risk will vary depending upon the experimental procedure, the unknowns, and the characteristics of the subject. In fact, the risk may at times be incapable of measurement because of the quantity or quality of these variables and because unexpected side effects can arise in even the most carefully designed experiment.<sup>40</sup> Until quite recently, without benefit of regulation, investigators themselves determined whether subjects

tion must begin before the experiment takes place. Further, in experimentation, subjects are asked to consent to these assessed risks.

37. Shapiro, *Legislating the Control of Behavior Control: Autonomy and the Coercive Use of Organic Therapies*, 47 S. CAL. L. REV. 237, 262 (1974). Shapiro listed a "set" of factors for determining the "intrusiveness" of an experimental technique:

- (i) the extent to which the effects of the therapy upon mentation are reversible; (ii) the extent to which the resulting psychic state is "foreign," "abnormal" or "unnatural" for the person in question, rather than simply a restoration of his prior psychic state (this is closely related to the "magnitude" or "intensity" of the change); (iii) the rapidity with which the effects occur; (iv) the scope of the change in the total "ecology" of the mind's functions; (v) the extent to which one can resist *acting* in ways impelled by the psychic effects of the therapy; and (vi) the duration of the change.

*Id.* (emphasis original) (footnotes omitted).

38. Note, *Conditioning and Other Technologies Used to "Treat?" "Rehabilitate?" "Demolish?" Prisoners and Mental Patients*, 45 S. CAL. L. REV. 616, 619-20 (1972). "Coerciveness" can be measured by examining (1) the "nature, extent and duration of the primary and side effects," (2) the subject's ability to affect the result once the experiment is undertaken, and (3) the amount of "actual physical intrusion." As an example, the Note contrasts psychotherapy and lobotomy. *Id.*

39. Although both Professor Shapiro, *supra* note 37, and the author of the Note, *supra* note 38, suggest the terms "intrusiveness" and "coerciveness" as measures of the legality of behavior modification techniques, these terms could be adopted for the measurement of risk. For example, Professor Shapiro's factor (vi), "the duration of the change" produced by the technique, and the Note's correlative "nature, extent and duration of the primary and side effects," also measure the magnitude of the physical or psychological harm that might be sustained by subjects in an experiment.

Other risk factors might include the general health of the individual subjects, the extent of prior experimentation on animals, the expertise of the investigator or the adequacy of emergency procedures. See generally Howard, *Issues in Human Experimentation*, 264 AM. J. OF THE MEDICAL SCIENCES 349 (1972).

40. The most significant variable is the subject himself. Altman, *Auto-experimentation: An Unappreciated Tradition in Medical Science*, 286 NEW ENG. J. MEDICINE 346, 350 (1972).

Drug testing in particular presents a situation in which risk evaluation is difficult. Thalidomide, found to be a safe and effective mild sedative in its experimental stage, was later used with disastrous effects on pregnant women. Barnes, *Clinical Studies in the Human: The Ethical and Scientific Problems*, 23 FERTILITY & STERILITY 593, 594 (1972).

should be exposed to various degrees of risk;<sup>41</sup> often the subjects were scarcely consulted.<sup>42</sup>

Experimental autonomy has had a long history.<sup>43</sup> A concurrent tradition has been auto-experimentation.<sup>44</sup> Indeed, some medical com-

41. See M. PAPPWORTH, *supra* note 34, at 12. Dr. Pappworth would have us contrast the physician whose fundamental concern is his patient, with the researcher whose primary, though not exclusive, concern is a medical problem. *Id.*

In B. BARBER, J. LALLY, J. MAKARUSHKA & D. SULLIVAN, *RESEARCH ON HUMAN SUBJECTS: PROBLEMS OF SOCIAL CONTROL IN MEDICAL EXPERIMENTATION* (1963), the authors surveyed medical investigators and found that the majority were able to balance the conflicting demands of pure science and humanity to patients. Certain circumstances, however, appeared to pressure investigators to place emphasis on the former demand. When a researcher has suffered "relative but deserved failure in the structure of the national and international biomedical research community," he may react by mass producing studies for publication in the search for recognition and esteem. *Id.* at 8. According to the authors, these studies tend to be undertaken with less than average sensitivity to ethical processes. *Id.* at 76. Likewise, a researcher who has experienced "relative but undeserved failure to get [favorable] treatment in the structure of rewards in a local-institutional setting," *id.* at 8, or who has a low rank, although his performance has been commensurate with those having achieved a higher rank, is more likely to have "permissive standards of behavior with regard to the use of human subjects in research." *Id.* at 80. The study concluded that

[a]ny attempt to reduce the amount of such deviance in biomedical research must, therefore, look to the effects of the structure of scientific competition as well as to the established values that are supposed to control researchers' behavior in this field.

*Id.*

42. The Tuskegee syphilis study is perhaps the most infamous of the experiments conducted without informed consent. In that study, the United States Public Health Service examined the long-range effects of untreated syphilis in poor, uneducated black residents of Macon County, Alabama. Although the subjects were told that they had "bad blood," they were never informed that they had syphilis. Nor were they ever asked if they desired to participate in the study. See Curran, *The Tuskegee Syphilis Study*, 289 *NEW ENG. J. MEDICINE* 730 (1973); Ratnoff, *supra* note 10, at 472-74, citing *Hearings on S.974, S.878 and S.J. Res. 71 Before the Subcomm. on Health of the Senate Comm. on Labor and Public Welfare (Study of Quality of Health Care—Human Experimentation)*, 93d Cong., 1st Sess., pt. 3, at 1036-42 (1973).

43. In both ancient Persia and Egypt, prisoners who had been condemned to death were "donated" by the king for purposes of scientific experimentation. See Beecher, *supra* note 15, at 3. See also Ivy, *supra* note 12, at 40.

44. Early experimenters used themselves as subjects both as a matter of convenience and as a showing of good faith. For example, in 1767 John Hunter injected himself with gonorrhea pus from a patient to prove how gonorrhea was transmitted. The experiment was typical of those of its day insofar as it was neither controlled nor preceded by animal experimentation. The faulty conclusion drawn by Hunter—when the inoculum grew gonorrhea and syphilis, he became convinced that the two diseases were identical—was a direct result of the faulty experimental design. Ivy, *supra* note 12, at 41; see Beecher, *supra* note 15, at 4. For a complete discussion of auto-experimentation, see Altman, *supra* note 40.

mentators have recommended that the two traditions be balanced to result in a "golden rule" for researchers: An investigator should not perform an experiment on another unless he is willing to perform the experiment on himself or on a member of his family.<sup>45</sup> Other commentators have scoffed at the concept, believing it unrealistic and inapplicable to the wide range of experiments that must be performed on physically or mentally ill patients.<sup>46</sup> Further, a researcher might lose much needed objectivity were he to participate in his own experiment.

Hans Jonas stated that "no scientist can be prevented from making himself a martyr for his science."<sup>47</sup> The question arises, however, whether there are some subjects who cannot be permitted "martyrdom" in any degree. The ability of the individual to give genuinely informed consent is crucial in making this determination.

### C. *Informed Consent*

Before a researcher may experiment on human subjects, he must impart to them information sufficient for rational decisionmaking about participation.<sup>48</sup> An investigator acts improperly if he proceeds with an experiment which, because of inadequate prior research, will expose the subject to an unreasonable number of unknown risks.<sup>49</sup> The justification for finding culpability is that under these circumstances a subject has no basis for electing to participate.<sup>50</sup>

Commentators have argued convincingly that a lay person is not capable of realistically assessing the risks involved in any given experiment.<sup>51</sup> They argue further that the many social pressures operating upon a lay individual prevent him from making decisions that are purely voluntary.<sup>52</sup> These perceptions emphasize the importance of placing a heavy burden on the experimenter to assure, to the greatest degree possible, that all risks have been minimized, that the essentials of the

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45. E.g., M. PAPPWORTH, *supra* note 34, at 189; Altman, *supra* note 40, at 351.

46. See, e.g., Note, *supra* note 34, at 969. See also Beecher, *supra* note 15, at 4.

47. Jonas, *supra* note 1, at 6.

48. Cf. *Canterbury v. Spence*, 464 F.2d 772, 786-87 (D.C. Cir.), cert. denied, 409 U.S. 1064 (1972) (disclosure of information about medical treatment).

49. See, e.g., Waltz & Scheuneman, *Informed Consent to Therapy*, 64 Nw. U.L. REV. 628 (1970).

50. Cf. *Canterbury v. Spence*, 464 F.2d 772, 786-89 (D.C. Cir.), cert. denied, 409 U.S. 1064 (1972).

51. See Ingelfinger, *Informed (But Uneducated) Consent*, 287 NEW ENG. J. MEDICINE 465 (1972); Jonas, *supra* note 1, at 24.

52. See Ingelfinger, *supra* note 51; Jonas, *supra* note 1, at 24.

experiment minus confusing detail have not only been disseminated but also comprehended, and that the subject has been permitted to make his decision in an atmosphere free from pressure. Thus, informed consent requires at least two essential elements: comprehension and voluntarism.<sup>53</sup>

The difficulty of meeting the standards of this formulation becomes evident upon examination of experimentation in the United States. According to Robert Q. Marston, former director of the National Institutes of Health, researchers turn to those groups whose continued availability is assured—hospitalized and institutionalized patients, prisoners, disadvantaged clinic patients, and students.<sup>54</sup> Each of these groups presents an acute problem with regard to voluntary participation in experimentation. One court has held that no individual can be totally free from the subtle coercions inherent in an institutionalized setting.<sup>55</sup> Special efforts must be made to insure that a patient's or an inmate's refusal to participate will not result in any kind of retribution.

Compounding the problem of voluntarism is the uncertain capacity of institutionalized mentally disabled persons to give consent that is competent. Competency refers to a person's ability to perform an act for which "jural capacity" is required.<sup>56</sup> Competency, therefore, should not be employed as a general term, but rather should be used in reference to the performance of a specific act of legal significance.<sup>57</sup> Although the

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53. For a discussion of informed consent to experimentation, see Capron, *Informed Consent in Catastrophic Disease Research and Treatment*, 123 U. PA. L. REV. 340 (1974); Dickens, *Contractual Aspects of Human Medical Experimentation*, 25 U. TORONTO L. REV. 406 (1975); Kidd, *Limits of the Right of a Person to Consent to Experimentation on Himself*, in Ladimer & Newman 233; Morse, *supra* note 7; Ratnof, *supra* note 10; Shapiro, *supra* note 37; Waltz & Scheuneman, *supra* note 49; Note, *supra* note 21; Note, *Medical Treatment and Human Experimentation: Introducing Illegality, Fraud, Duress and Incapacity to the Doctrine of Informed Consent*, 6 RUTGERS-CAMDEN L.J. 538 (1975).

54. Marston, *Research on Minors, Prisoners and the Mentally Ill*, 288 NEW ENG. J. MEDICINE 158, 158 (1973).

55. *Kaimowitz v. Michigan Dep't of Mental Health*, Civil No. 73-19434-AW (Cir. Ct., Wayne County, Mich. July 10, 1973), reprinted in A. BROOKS, *supra* note 25.

56. Hardisty, *Mental Illness: A Legal Fiction*, 48 WASH. L. REV. 735, 740 (1973). See generally J. GLOVER, *RESPONSIBILITY* (1970); T. SZASZ, *THE MYTH OF MENTAL ILLNESS* (1961).

57. For example, an individual may be found incompetent to execute a will, make a contract, marry, sue or be sued, drive, vote, or practice a profession. For a critical view of the limitation of rights resulting from adjudication of "incompetency," or "mental illness," see 2 B. ENNIS & P. FRIEDMAN, *LEGAL RIGHTS OF THE MENTALLY HANDICAPPED* 1015-92 (1973).

institutionalization of a patient for a particular mental disorder is often equated with general incompetence to make any major decision, as a matter of both medicine and law this view is incorrect.<sup>58</sup>

Two commentators, George Alexander and Thomas Szasz, observed that

[t]he methods used for adjudication of incompetency, and the criteria by which incompetence is judged, vary widely. . . . There is little accord among the states as to the weight to be given previous or continuing commitment to a mental hospital, a prior adjudication of incompetency, or acts which the court may view as abnormal.<sup>59</sup>

Even if "[h]ow crazy is crazy" and the point at which a person becomes able to give informed consent<sup>60</sup> can be determined, there remains the problem whether such consent should be accepted. There is general agreement that experimentation on mentally disabled persons should be avoided whenever possible,<sup>61</sup> but opinions diverge when an absolute prohibition is recommended.<sup>62</sup> Limitations have been suggested,<sup>63</sup> but the matter remains controversial. Some institutionalized mentally disabled persons are competent to decide to participate in research. Such persons should not be deprived of the opportunity to contribute to scientific and medical advancement simply because they are institutionalized. Concurrently, mechanisms should be developed to insure that voluntary and informed consent be obtained. The most stringent limitations on experimentation should be reserved for cases in which consent

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58. For a comprehensive study of the relationship between institutionalization and incompetency, see *THE MENTALLY DISABLED AND THE LAW* 250-65 (rev. ed. S. Brakel & R. Rock 1971). See generally R. ALLEN, E. FERSTER & H. WEIHOFEN, *MENTAL IMPAIRMENT AND LEGAL INCOMPETENCY* (1968).

59. Alexander & Szasz, *From Contract to Status Via Psychiatry*, 13 SANTA CLARA LAW. 537, 540 (1973).

60. Lasagna, *Special Subjects in Human Experimentation*, in Freund 262, 272.

61. See Ivy, *supra* note 12, at 48; Jonas, *supra* note 1, at 20; Kidd, *supra* note 53, at 237; Lasagna, *supra* note 60, at 272; Morse, *supra* note 7, at 756. See also M. PAPPWORTH, *supra* note 34, at 52-60.

62. Compare Jaffe, *supra* note 1, at 48, with Morse, *supra* note 7, at 756.

63. See, e.g., Marston, *supra* note 54. The author supported the HEW proposed policy:

In hospitals for the mentally ill and retarded, the research supported [by HEW and NIH] would be restricted to the following: research that is directly concerned with the issues of mental illness, mental health or mental retardation, or that will potentially benefit a class of persons commonly confined to a hospital for the mentally ill or retarded, or will lead to such knowledge that may reasonably be expected to reduce the need for hospitalization for mental illness or retardation.

*Id.* at 159.

can be obtained only from a close relative or guardian. Even in that situation, experimentation should not be precluded.

### III. ETHICAL STANDARDS

Experimentation has never taken place within a moral vacuum.<sup>64</sup> Besides the "golden rule,"<sup>65</sup> attempts have been made at least from the times of Hippocrates to formulate ethical standards for medical practice and experimentation. Much of the Hippocratic Oath is today archaic, but the principles that a physician must act according to the best of his ability and judgment for the benefit of his patients and must abstain from "whatever is deleterious and mischievous" are still tenable.<sup>66</sup>

A more detailed code arose in reaction to atrocities revealed during the Nuremberg trials. The Military Tribunal was shocked to learn that extensive experimentation had been carried out, not as "the isolated and casual acts of individual doctors and scientists working solely on their own responsibility" but rather as a "product of coordinated policy-making and planning at high governmental, military, and Nazi party levels."<sup>67</sup> General Telford Taylor enumerated ten principles that

64. There have been, however, sporadic exceptions to this generalization. See note 67 *infra* and accompanying text.

65. See notes 43-46 *supra* and accompanying text.

66. Hippocratic Oath, reprinted in J. KATZ, EXPERIMENTATION WITH HUMAN BEINGS 311 (1972):

I swear by Apollo the physician, and Aesculapius and Health, and All-heal, and all the gods and goddesses, that, according to my ability and judgment, I will keep this Oath . . . [B]y precept, lecture, and every other mode of instruction, I will impart a knowledge of the Art to my own sons, and those of my teachers, and to disciples bound by a stipulation and oath according to the law of medicine, but to none others. I will follow that system of regimen which, according to my ability and judgment, I consider for the benefit of my patients, and abstain from whatever is deleterious and mischievous. I will give no deadly medicine to anyone if asked, nor suggest any such counsel: and in like manner I will not give to a woman a pessary to produce abortion. With purity and with holiness I will pass my life and practise my Art. I will not cut persons labouring under the stone, but will leave this to be done by men who are practitioners of this work. Into whatever houses I enter, I will go into them for the benefit of the sick, and will abstain from every voluntary act of mischief and corruption; and, further, from the seduction of females or males, or freemen or slaves. Whatever, in connection with my professional practice, or not in connection with it, I see or hear, in the life of men, which ought not to be spoken of abroad, I will not divulge, as reckoning that all such should be kept secret. While I continue to keep this Oath unviolated, may it be granted to me to enjoy life and the practice of the Art, respected by all men, in all times. But should I trespass and violate this Oath, may the reverse be my lot.

67. J. KATZ, *supra* note 66, at 292, 305, reprinting excerpts from 2 TRIALS OF WAR

formed the basis for finding Nazi culpability.<sup>68</sup> This "Nuremberg

**CRIMINALS BEFORE THE NUREMBERG MILITARY TRIBUNALS (1948) (United States v. Karl Brandt).**

Received into evidence at the War Crimes trial, for example, was the following letter:

This research which deals with the reaction of the human organism at great heights, as well as with manifestations caused by prolonged chilling of the human body in cold water, and similar problems which are of vital importance to the Air Force, in particular, can be performed by us with particular efficacy because I personally assumed the responsibility for supplying asocial individuals and criminals, who only deserve to die, from concentration camps for these experiments. TMWC, IV, 206-7.

Letter from Heinrich Himmler to Field Marshal Milch, Nov. 1942, reprinted in W. HARRIS, *TYRANNY ON TRIAL; THE EVIDENCE AT NUREMBERG* 427 (1954). These "experiments" had been described to Himmler by a medical officer of the Luftwaffe as so dangerous that no one would volunteer for them. *Id.* at 424. Other "experiments" included the clinical observation of condemned prisoners shot with poisoned bullets and anatomical studies that began with the taking of personal data from a living person. After the "subsequently induced death of the Jew," the physician severed the head and shipped it to a lab for further study. *Id.* at 429. See R. GALLAGHER, *NUREMBERG: THE THIRD REICH ON TRIAL* 159-205 (1961); J. KATZ, *supra* note 66, at 292-306; A. MITCHERLICH & F. MIELKE, *DOCTORS OF INFAMY: THE STORY OF THE NAZI MEDICAL CRIMES* (1949).

68. [Certain basic principles must be observed in order to satisfy moral, ethical, and legal concepts:

1. The voluntary consent of the human subject is absolutely essential. . . .
  2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.
  3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.
  4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
  5. No experiment should be conducted where there is an *a priori* reason to believe that death or disabling injury will occur; except perhaps, in those experiments where the experimental physicians also serve as subjects.
  6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.
- [7.] Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.
8. The experiment should be conducted only by scientifically qualified persons. . . .
  9. The human subject should be at liberty to bring the experiment to an end . . . .
  10. The scientist in charge must be prepared to terminate the experiment at any stage if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

J. KATZ, *supra* note 66, at 292, 305, reprinting excerpts from 2 TRIALS OF WAR CRIMINALS BEFORE NUREMBERG MILITARY TRIBUNALS (1948) (United States v. Karl Brandt).

Code" has been described as "admirable in intent,"<sup>69</sup> too black and white to be useful,<sup>70</sup> and "too ambiguous in language" to be workable.<sup>71</sup> Because its overriding purpose was to prevent a recurrence of the kinds of clearly reprehensible acts performed by Nazi doctors and scientists in the name of the Third Reich, the Nuremberg Code gave little consideration to the need for medical progress.<sup>72</sup> While the Code had the force of neither a case nor a statute, it was for almost twenty years the "primary American articulation of standards governing human experimentation."<sup>73</sup>

In an attempt to remedy the deficiencies of the Nuremberg Code, the World Medical Association adopted the Declaration of Helsinki.<sup>74</sup> The Declaration distinguished between therapeutic and nontherapeutic investigation, and provided five "Basic Principles."<sup>75</sup> Like the Nuremberg

69. Ratnoff & Smith, *supra* note 24, at 673.

70. Comment, *supra* note 7, at 1078, citing *Editorial*, 270 NEW ENG. J. MEDICINE 1014 (1964).

71. Ratnoff & Smith, *supra* note 24, at 673-74. See PAPPWORTH, *supra* note 34, at 199-200; Beecher, *supra* note 15, at 28-33.

72. Beecher, *supra* note 15, at 29.

73. Note, *supra* note 21, at 103.

74. Reprinted in 2 BRIT. MEDICAL J. 177 (1964) and 271 NEW ENG. J. MEDICINE 473 (1964).

75. I. Basic Principles

1. Clinical research must conform to the moral and scientific principles that justify medical research, and should be based on laboratory and animal experiments or other scientifically established facts.

2. Clinical research should be conducted only by scientifically qualified persons and under the supervision of a qualified medical man.

3. Clinical research cannot legitimately be carried out unless the importance of the objective is in proportion to the inherent risk to the subject.

4. Every clinical research project should be preceded by careful assessment of inherent risks in comparison to foreseeable benefits to the subject or to others.

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

II. Clinical Research Combined with Professional Care

1. In the treatment of the sick person the doctor must be free to use a new therapeutic measure if in his judgment it offers hope of saving life, re-establishing health, or alleviating suffering.

If at all possible, consistent with patient psychology, the doctor should obtain the patient's freely given consent after the patient has been given a full explanation. In case of legal incapacity consent should also be procured from the guardian; in case of physical incapacity the permission of the legal guardian replaces that of the patient.

2. The doctor can combine clinical research with professional care, the objective being the acquisition of new medical knowledge, only to the extent that clinical research is justified by its therapeutic value for the patient.

Code, the Declaration of Helsinki focused on the concepts of consent and risk-benefit ratio. While the Declaration is not without its critics,<sup>76</sup> numerous American professional societies have adopted its tenets.<sup>77</sup>

In 1966, Henry Beecher expressed several reasons why it was imperative that additional consideration be given to ethical problems in experi-

### III. Non-therapeutic Clinical Research

1. In the purely scientific application of clinical research carried out on a human being it is the duty of the doctor to remain the protector of the life and health of that person on whom clinical research is being carried out.

2. The nature, the purpose, and the risk of clinical research must be explained to the subject by the doctor.

3a. Clinical research on a human being cannot be undertaken without his free consent, after he has been fully informed; if he is legally incompetent the consent of the legal guardian should be procured.

3b. The subject of clinical research should be in such a mental, physical, and legal state as to be able to exercise fully his power of choice.

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

4a. The investigator must respect the right of each individual to safeguard his personal integrity, especially if the subject is in a dependent relationship to the investigator.

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

Declaration of Helsinki, June, 1964, reprinted in 2 BRIT. MEDICAL J. 177 (1964) and 271 NEW ENG. J. MEDICINE 473-74 (1964).

76. See, e.g., Ingelfinger, *Ethics of Experiments on Children*, 288 NEW ENG. J. MEDICINE 791 (1973).

77. These societies include the American Medical Association (AMA), the American Federation for Clinical Research, the American Society for Clinical Investigation, and the American College of Physicians and Surgeons. Comment, *supra* note 7, at 1079.

The AMA has long opposed any outside control which, it maintains, would threaten the "professionalism" of the American physician and consequently the quality of health care. According to President Malcolm Todd, the AMA feels it must "keep fighting for the preservation of American medicine as an individually motivated science . . ." Todd, *To Preserve Our Professional Freedoms* . . . , 3 PRISM, Feb. 1975, at 46. Part of that fight has been a public relations effort to "retain—and augment—the people's confidence in our medical leadership . . ." *Id.* The AMA has also attempted to impose self-regulation first. In addition to the Declaration of Helsinki, the AMA adopted Principles of Medical Ethics, analogous to the Code of Professional Responsibility of the American Bar Association. These principles are not disciplinary rules, but rather "standards by which a physician may determine the propriety of his conduct." *Opinions and Reports of the Judicial Council* iii (1969), in J. KATZ, *supra* note 68, at 313. Theoretically, the principles should enable clinical investigators to clarify their ethical responsibilities to patients. *But cf.* B. BARBER, J. LALLY, J. MAKARUSHKA, & D. SULLIVAN, *supra* note 41.

mentation.<sup>78</sup> In support of his contention that a major problem existed, Dr. Beecher outlined six categories of experiments and listed dozens of abuses that not only had occurred in American experiments but also had been published and thus given recognition by reputable professional journals.<sup>79</sup> Dr. Beecher did not identify the experiments, but recognizable among the examples was the Willowbrook hepatitis experiment, in which parents of mentally retarded inmates consented, apparently without information regarding the "appreciable hazards," to the artificial induction of hepatitis in their children.<sup>80</sup> Dr. Beecher also described the Jewish Chronic Disease Hospital experiment. There, patients hospitalized for treatment of other diseases were told merely that they would be injected with "some cells." The word cancer was omitted because the researchers, deeming the experiment safe, felt that a patient might then refuse to participate.<sup>81</sup>

The underlying theme of the many abuses Dr. Beecher described was the experimenters' failure to obtain voluntary and adequately informed consent. The Willowbrook experience points up an additional problem. Institutionalized mentally retarded children were chosen for hepatitis studies because they presented a stable population that could be followed easily and because rampant hepatitis already posed a distinct threat to all newcomers to the institution.<sup>82</sup> The patient-subjects, however, had no legal capacity to give consent. On the question of consent, the Nuremberg Code is ambiguous: "The voluntary consent of the human subject is absolutely essential. This means that the person involved *should* have legal capacity to give consent."<sup>83</sup> The Declaration

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78. See Beecher, *supra* note 31.

79. Dr. Beecher characterized the experiments as follows: (1) studies of withholding known effective treatment; (2) studies of therapy in use, and corresponding nontherapeutic application; (3) physiologic studies; (4) studies to improve the understanding of disease; (5) technical studies of disease; (6) bizarre studies. *Id.* at 1356-59.

80. *Id.* at 1358. The Willowbrook experiment continues to cause controversy. See, e.g., Lasagna, *supra* note 60, at 271; Ingelfinger, *supra* note 76, at 792; Dolan, *Ethics of Human Experimentation* (letter to the editor), 289 NEW ENG. J. MEDICINE 46 (1973); Plotkin, *Ethics of Human Experimentation* (letter to the editor), 289 NEW ENG. J. MEDICINE 593 (1973); Baumslag, Huskins, Nixon, *Ethical Principles in Human Experimentation* (letters to the editor), 288 NEW ENG. J. MEDICINE 1247 (1973).

81. Beecher, *supra* note 31, at 1358; Ratnoff, *supra* note 10, at 487; Note, *supra* note 21, at 99-100.

82. Lasagna, *supra* note 60, at 271.

83. J. KATZ, *supra* note 66, at 292, 306, reprinting excerpts from 2 TRIALS OF THE WAR CRIMINALS BEFORE THE NUREMBERG MILITARY TRIBUNALS (1948) (United States v. Karl Brandt).

of Helsinki provides no clearer guide. While these guidelines state unequivocally that nontherapeutic clinical research "cannot" be undertaken without the fully informed, free consent of the subject, they also provide that the consent of the legal guardian of an incompetent "should" be obtained. The Declaration further states that "[t]he subject of clinical research *should* be in such a mental, physical, and *legal* state as to be able to exercise fully his power of choice."<sup>84</sup> These statements, in combination, have been taken to preclude all nontherapeutic experimentation on children and mental incompetents.<sup>85</sup> Although the Declaration allows therapeutic experimentation even when the patient is incapable of giving consent,<sup>86</sup> it gives no insight into the distinction between therapeutic and nontherapeutic experiments.<sup>87</sup>

The professional ethical codes have been criticized as ineffectual because they lack the force of law.<sup>88</sup> It is clear that however well-meaning and ethical the vast majority of researchers, the ultimate decision on the justifiability of an experiment should not be made by an individual whose interests are contrary to the interests of the subjects,<sup>89</sup> and perhaps to those of society. Recognizing this need, commentators have called for a legislative solution.<sup>90</sup>

#### IV. CASE LAW

In addition to the absence of legislative attempts to regulate experimentation,<sup>91</sup> commentators have noted the remarkable lack of case law

84. Declaration of Helsinki, *reprinted in* 2 BRIT. MEDICAL J. 177 (1964), 271 NEW ENG. J. MEDICINE 473 (1964) (emphasis added).

85. See Ingelfinger, *supra* note 76, at 791.

86. See note 75 *supra*. Senator Hubert Humphrey questioned whether the parents of the children involved had given truly voluntary consent. Ratnoff, *supra* note 10, at 490, citing *Hearings on S. 974, S. 878, and S.J. Res. 71 Before the Subcomm. on Health of the Senate Comm. on Labor and Public Welfare (Study of Quality of Health Care—Human Experimentation)*, 93d Cong., 1st Sess. pt. 1, at 179 (1973).

87. For an explanation of classifications of experiments, see notes 28-32 *supra* and accompanying text.

88. See M. PAPPWORTH, *supra* note 34, at 199.

89. The researcher's primary interest, is problem solving while the subject's overriding concern is his own well-being. Because of his desire to proceed with the experiment, the researcher may minimize the risk to subjects. See generally B. BARBER, J. LALLY, J. MAKARUSHKA & D. SULLIVAN, *supra* note 41; M. PAPPWORTH, *supra* note 34.

90. *Id.* at 200. See also Ingelfinger, *supra* note 76, at 791 (broadly based system should be set up); Jaffe, *supra* note 1, at 205 (standards should allow leeway for exercise of judgment); Comment, *supra* note 7, at 1091 (current regulations leave too much to discretion of researcher).

91. *But see* note 142 *infra* and accompanying text.

on the issue.<sup>92</sup> The earliest reported case, *Slater v. Baker*,<sup>93</sup> was a special action on the case against a surgeon and an apothecary for using "an heavy steel thing that had teeth, and would stretch or lengthen the leg"<sup>94</sup> after it was set. At that time, the accepted treatment was to compress the leg once the "callous" had formed. The court held the defendants liable both for ignorant and unskillful practice in acting "contrary to the known rule and usage of surgeons," and for doing so without first telling the patient "what is about to be done to him, so that he may take courage and . . . undergo the operation."<sup>95</sup>

*Slater* created the rule that experimentation is undertaken at the physician's peril. *Carpenter v. Blake*<sup>96</sup> is the leading American case approving the "physician's peril" doctrine:

[I]t is incumbent on surgeons called to treat such an injury, to conform to the system of treatment thus established; and if they depart from it, they do so at their peril.<sup>97</sup>

The court conceded that such a rule might cause the patient to lose the benefits of recent cures and improvements in treatment, but dismissed the problem as "more apparent then [*sic*] real."<sup>98</sup> Additionally, the court stressed the need for a standard for determining the propriety of a particular treatment: "[O]therwise experience will take the place of skill, and the reckless experimentalist the place of the educated, experienced practitioner."<sup>99</sup> Although the court should have confined itself to the issue at hand, the adherence to the established system of treatment,

92. See, e.g., *Beecher*, *supra* note 15, at 25; *Ladimer*, *supra* note 1, at 186; *Comment*, *supra* note 7, at 1071.

As recently as 1953 it was suggested that no case law developed because the legal maxim "De minimus non curat lex" was operating; "an extra drop of blood to build up a control group for a research study, or the use of tissue that has been properly severed would not be condemned by the court." *Kidd*, *supra* note 53, at 236. *Kidd* cautioned restraint, however, in the name of good public relations. *Id.*

93. 95 Eng. Rep. 860 (K.B. 1767).

94. *Id.* at 861.

95. *Id.* at 862.

96. 60 Barb. 488 (N.Y. Sup. Ct. 1871), *rev'd on other grounds*, 50 N.Y. 696 (1872).

97. *Id.* at 514.

98. It must be conceded that if a surgeon is bound, at the peril of being liable for malpractice, to follow the modes of treatment which writers and practioners have prescribed, the patient may lose the benefits of recent improvements in the treatment of diseases, or discoveries in science, by which new remedies have been brought into use . . . .

*Id.* at 523.

99. *Id.*

the court in *Carpenter*, as that in *Slater*, labeled such departure "experimentation."

*Carpenter* laid the groundwork for a line of cases<sup>100</sup> that define experimentation to include malpractice and quackery as well as failure to conform to accepted practices.<sup>101</sup> This common law left the physician with the inherent dilemma expressed in the summary of the *Carpenter* opinion:

The [physician's peril] rule protects the community against reckless experiments, while it admits the adoption of new remedies and modes of treatment only when their benefits have been demonstrated, or when, from the necessity of the case, the surgeon or physician must be left to the exercise of his own skill and experience.<sup>102</sup>

While doctors must strive to do what is best for their patients, they may not safely expand the frontiers of medicine. New therapies in medicine become approved, but physicians who experiment to demonstrate their new procedures' safety and effectiveness are required by *Carpenter* to do so at their own risk.

As recently as 1935, a modified version of the physician's peril doctrine was reiterated:

We recognize the fact that if the general practice of medicine and surgery is to progress, there must be a certain amount of experimentation carried on; but such experiments must be done with the knowledge and consent of the patient or those responsible for him and must not vary too radically from the accepted method of procedure.<sup>103</sup>

Virtually all the case law on experimentation involves negligent therapy, failure to obtain adequate consent, and therapeutic rather than nontherapeutic experimentation.<sup>104</sup> Thus, although physicians may be

100. See, e.g., *Kershaw v. Tilbury*, 214 Cal. 679, 8 P.2d 109 (1932); *Langford v. Kosterlitz*, 107 Cal. App. 175, 290 P. 80 (1930); *Brown v. Hughes*, 94 Colo. 295, 30 P.2d 259 (1934); *Jackson v. Burnham*, 20 Colo. 532, 39 P. 577, 580 (1895); *Allen v. Voje*, 114 Wis. 1, 89 N.W. 924, 932 (1902).

101. See *Cady*, *supra* note 19, at 172; *Kidd*, *supra* note 53, at 235; *Ladimer*, *supra* note 1, at 186; Note, *supra* note 21, at 112.

102. *Carpenter v. Blake*, 60 Barb. 488, 524 (N.Y. Sup. Ct. 1871), *rev'd on other grounds*, 50 N.Y. 696 (1872).

103. *Fortner v. Koch*, 272 Mich. 273, 282, 261 N.W. 762, 765 (1935). But see *Adams & Shea-Stonum, Toward a Theory of Control of Medical Experimentation with Human Subjects: The Role of Compensation*, 25 CASE W. RES. L. REV. 604, 635 (1975) (interpreting *Fortner*).

104. See cases cited note 100 *supra*. Other cases, having arisen in unusual contexts, supply only dicta. For example, the holding of *Hyman v. Jewish Chronic Disease Hosp.*, 21 App. Div. 2d 495, 251 N.Y.S.2d 818 (2d Dept. 1964), *rev'd*, 15 N.Y.2d 317,

held liable for harm to their patients regardless of how ably they conduct carefully controlled experiments, no judicial standards have been developed for experiments that are clearly necessary for the welfare of society. Certainly since *Slater v. Baker*<sup>105</sup> in 1767, more sophisticated legal guidelines should have evolved.<sup>106</sup>

## V. HEW REGULATIONS

The Secretary of Health, Education and Welfare is authorized by 5 U.S.C. § 301<sup>107</sup> to promulgate regulations for the "performance of [HEW] business." In recent years, HEW has exercised this authority to protect human subjects of research projects supported by the National Institutes of Health. The 1971 *Institutional Guide to HEW Policy on Protection of Human Subjects*<sup>108</sup> was prompted by increasing concern about "the possibility of untoward events" induced by the growing amount of research conducted in the United States.<sup>109</sup> According to a Division of Research Resources report, however, NIH was not considered the proper body to formulate "the authoritarian position on ethical bounds."<sup>110</sup> Thus, the initial emphasis was placed on safeguarding the rights and welfare of subjects through a system of local institutional review. Each institution carrying on research funded by NIH was required to establish a committee to oversee such projects.<sup>111</sup>

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258 N.Y.S.2d 397, 206 N.E.2d 338 (1965), related to the confidentiality of chart notations concerning cancer experiments for which inadequate consent was obtained. *New York State Ass'n for Retarded Children v. Rockefeller*, 357 F. Supp. 753, 764 (E.D.N.Y. 1973) discussed the inmates' right to protection against harm at Willowbrook in terms of being "entitled to at least the same living conditions as prisoners." The children's rights vis-a-vis experimentation are not mentioned.

Some potentially precedent-setting cases may have been settled out of court, as was the suit against the federal government brought by survivors and families of deceased subjects who went untreated in the Tuskegee syphilis experiment. *See* TIME, Feb. 17, 1975, at 80.

105. 95 Eng. Rep. 860 (K.B. 1767).

106. *See* Beecher, *supra* note 15, at 27; Jaffe, *supra* note 1, at 199; Kidd, *supra* note 53, at 235; Ebersold, *supra* note 14, at 169; Kaplan, *supra* note 18, at 90; Comment, *supra* note 7, at 1071.

107. *See* note 8 *supra*.

108. *See* note 11 *supra*.

109. Marston, *supra* note 10, at 597.

110. *Id.*

111. INSTITUTIONAL GUIDE, *supra* note 11, at 1. The INSTITUTIONAL GUIDE announced an HEW policy of awarding grants only to researchers affiliated with institutions willing to assume responsibility for providing the necessary review. *Id.*

HEW policy, as expressed in the *Institutional Guide*, was intended to be flexible, depending ultimately upon the "common sense and sound professional judgment of reasonable men."<sup>112</sup> The *Institutional Guide* provided for a two-step review procedure. First, the institutional review committee identified "those projects or activities which involve subjects who may be at risk." "At risk" was defined broadly as exposure to the possibility of physical, psychological, sociological, or other harm incurred as a result of "any activity which goes beyond the application of those established and accepted methods necessary to meet [the subject's] needs."<sup>113</sup> If the committee determined that the project involved only established procedures necessary for the well-being of the subject, review ended. If the institutional committee found that the project entailed more, the subjects were said to be "at risk," and review "expanded to include the issues of the protection of the subject's rights and welfare, of the relative weight of risks and benefits, and of the provision of adequate and appropriate consent procedures."<sup>114</sup>

The institutional committee was intended to be more than a peer review board, although in practice, it generally was not.<sup>115</sup> To inject community standards into decisions, the *Institutional Guide* stressed the importance of multidisciplinary representation on the review committees.<sup>116</sup> After local institutional acceptance of research projects, two further stages of review, both at the national level, were required.<sup>117</sup>

Several major objections were made to the system of review imposed by HEW policy. First, if a subject were legally incompetent to give consent, the HEW policy permitted "his authorized representative"<sup>118</sup> to consent to his participation.<sup>119</sup> Second, inquiry into consent of any

112. D. Chalkley, *Introduction*, INSTITUTIONAL GUIDE iii.

113. INSTITUTIONAL GUIDE 2. "Activity" included research, development, demonstration (apparently intended to cover activity for the benefit of trainees) or "other activities supported by DHEW funds." *Id.* Methods become "established and accepted" as a matter of law through espousal by professional societies or by common professional judgment. *Id.* at 3. The needs of a subject were to be ascertained by "an attending professional." *Id.*

114. *Id.* at 5.

115. See B. BARBER, J. LALLY, J. MAKARUSHKA & D. SULLIVAN, *supra* note 41, at 194; Mishkin, *Multidisciplinary Review for the Protection of Human Subjects in Biomedical Research: Present and Prospective HEW Policy*, 54 B.U.L. REV. 278, 281 (1974); Welt, *Reflections on the Problems of Human Experimentation*, 25 CONN. MEDICINE 75 (1961).

116. INSTITUTIONAL GUIDE 4.

117. See Mishkin, *supra* note 115, at 281.

118. INSTITUTIONAL GUIDE 7.

119. Mishkin pointed out that the interests of parents and other legal representatives

kind became unnecessary if the subject were determined not to be "at risk." Although "risk" was defined quite broadly, gray areas within the realm of professional judgment about established and accepted methods, as well as methods necessary to meet the subjects' needs,<sup>120</sup> arguably left pockets of unsupervised discretion between experimentation and treatment.<sup>121</sup> Third, the HEW policy failed to differentiate among kinds of research subjects. Although researchers traditionally have favored using persons confined in institutions,<sup>122</sup> such persons may lack the capacity to give truly voluntary consent. Moreover, ascertaining competence to give understanding consent has compounded the problem of using institutionalized subjects.<sup>123</sup> Fourth, the *Institutional Guide* committed to the discretion of the institutional committee the determination of the extent to which risks to the subject could be outweighed by the hypothesized benefits to the individual and to society.<sup>124</sup> Finally, although HEW presented an ethical model for all experimentation practiced in the United States,<sup>125</sup> the HEW regulations applied only to research receiving NIH funding. Furthermore, HEW's sole sanction was the withdrawal of funds for ongoing and future research projects.<sup>126</sup>

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are sometimes antagonistic to those of their wards, especially when subjects are institutionalized at great emotional and monetary cost. Mishkin, *supra* note 115, at 283. See also note 80 *supra* and accompanying text.

120. See note 113 *supra*.

121. See, e.g., Norton, *When Does an Experimental Innovative Procedure Become an Accepted Procedure?*, 38 PHAROS 161 (1975).

122. Many studies require a stable population for long-term follow-up. See text accompanying note 83 *supra*.

123. There is a popular belief that any individual requiring commitment must be incompetent to make any decisions at all, particularly those relating to his own therapy. This belief is erroneous. See Shapiro, *supra* note 37, at 308; text accompanying notes 56-58 *supra*.

It has been suggested, however, that even when an investigator fully complies with prescribed procedures for obtaining consent, the chances are excellent that the subject has not adequately understood that to which he has consented. Were it possible to relay to the subject "the inconveniences and hazards that he will have to undergo [in the context of] the improvements that the research project may bring to the management of his disease in general and to his own case in particular," the amount of detail would undoubtedly confuse him. Ingelfinger, *supra* note 51, at 465.

124. See generally Katz, *Who Is to Keep Guard Over the Guards Themselves?*, 23 FERTILITY & STERILITY 604 (1972). Dr. Katz pointed up the need for scholarly inquiry into questions of harm, risk and benefit, and authority to make decisions about them.

125. See *Kaimowitz v. Michigan Dept. of Mental Health*, Civil No. 73-19434-AW (Cir. Ct., Wayne Co., Mich. July 10, 1973), reprinted in A. BROOKS, *supra* note 25.

126. Thus, privately funded institutions were not affected by HEW's regulatory efforts. Sources of private funding include private foundations and drug companies.

Despite its alleged shortcomings, the HEW policy was declared "successful" in 1972 by the Director of NIH.<sup>127</sup> That same year, however, he expressed the belief that some subjects needed additional protection.<sup>128</sup> After further study, Subtitle A of Title 45 of the *Code of Federal Regulations* was amended, effective July 1, 1974, by adding a new Part 46. Although the new rules postpone consideration of additional protections for specified subjects,<sup>129</sup> they emphasize the risks involved in experimentation, particularly with regard to informed consent procedures.<sup>130</sup> In addition to assuring that subjects are fully informed, the new regulations require local Institutional Review Boards to weigh the risks and benefits of a proposed "research, development or related activity"<sup>131</sup> before determining that "the benefits favor a decision to allow the subject to accept these risks."<sup>132</sup> The regulations also require an assessment of the protection afforded the subject against known risks.<sup>133</sup> The basic mode of implementation is again through the local Institutional Review Boards; no grant can be awarded unless a

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Mead suggested that more stringent restraints must be imposed when government funds are involved than when research is supported by private sources. The reason is partly political, but also is social: public funding implies public support, responsibility, and sanction. Mead, *supra* note 13, at 163.

127. Marston, *supra* note 10, at 599.

128. Mishkin, *supra* note 115, at 281, citing address by Robert Q. Marston, Medical Science, the Clinical Trial and Society, University of Virginia, Nov. 10, 1972, excerpted in HASTINGS CENTER REP., No. 3, 1973, at 1-4.

129. These included minors, the mentally ill, the mentally retarded, and prisoners. See 39 Fed. Reg. 18914 (1974).

130. *Id.*

131. 45 C.F.R. § 46.103(b) (1975).

132. 39 Fed. Reg. 18914 (1974) (emphasis added). Thus, there appear to be some risks to which no one can consent, regardless of any capacity to understand.

It has been suggested that if the experiment is poorly designed so that results will be unreliable or useless, risk to subjects, no matter how slight, will be unacceptable. See Cowan, *supra* note 17, at 550; Curran, *supra* note 2, at 441; Freund, *Introduction*, 98 DAEDALUS x (1969) (symposium on ethics of human experimentation). This proposition raises some serious questions. A review committee, composed of community representatives and professionals from various disciplines may be unqualified to judge complex research designs. Second, such review might infringe upon academic freedom if review committees were given the power to prevent experimentation, based on their assessment that an experimentator would not derive valid results or significant information from a procedure. If the experiment involves too many unknown risk factors, however, no subject should be permitted to participate. See Waltz & Scheuneman, *supra* note 49, at 632. Note that in each case the decision is to be made by a review committee, not by the investigator or the subject. Howard, *Issues in Human Experimentation*, 264 THE AM. J. OF THE MEDICAL SCIENCES 349, 350 (1972). See also J. KATZ, *supra* note 66, at 675; Kidd, *supra* note 53, at 233.

133. 39 Fed. Reg. 18914 (1974).

Review Board of the institution seeking aid has first "submitted to DHEW a certification of [its] review and approval in accordance with the [regulations]."<sup>134</sup>

On August 23, 1974, HEW proposed further protective regulation for subjects whose ability to give informed consent "is or may be absent or limited."<sup>135</sup> Subpart E would provide "additional protections" to the "institutionalized mentally disabled."<sup>136</sup> The proposed rules would allow such subjects to participate only in research "which is most likely to be of assistance to them or to persons similarly disabled."<sup>137</sup> HEW deems this limitation necessary to prevent the infringement of personal rights and freedom of choice associated with involuntary institutionalization. Additionally, HEW can thus minimize the problems inherent in determining the potential subjects' ability to comprehend generally and appreciate the significance of the risks involved in an experiment.<sup>138</sup> Although limiting research on institutionalized mentally disabled patients to "the disease entities affecting individual subjects" may not be beneficial to the mentally disabled as a class,<sup>139</sup> HEW reasoned that "the possible risks of using the mentally disabled in [unrelated] research outweigh its advantages."<sup>140</sup>

While the proposed rules break new ground in the protection of research subjects, the adopted rules and regulations are essentially a codification, with a few definitional or editorial changes, of policies previously expressed in the *Institutional Guide*. Reinforcing HEW's belief that it was not the appropriate agency to formulate detailed guidelines of universal applicability was the almost simultaneous signing into law of the National Research Act,<sup>141</sup> which established a National Commission for the Protection of Biomedical and Behavioral Research. The Act requires the Commission to articulate fundamental ethical principles governing research on human subjects and to develop guidelines to assure that research is conducted in compliance with those

134. 45 C.F.R. § 46.102 (1975).

135. 39 Fed. Reg. 30648 (1974). By designating the previously adopted rules (published on May 30 and effective July 1, 1974) as "Subpart A," proposed Subparts B through F would supplement the original rulemaking.

136. *Id.* See also 39 Fed. Reg. 30655 (1974).

137. 39 Fed. Reg. 30648 (1974).

138. 39 Fed. Reg. 30655 (1974).

139. See text accompanying notes 162-63 *infra*.

140. 39 Fed. Reg. 30652 (1974).

141. 42 U.S.C.A. §§ 2891-1 to -3 (1975).

principles.<sup>142</sup> Thus, most of the problems found in the earlier policy will continue to exist until the Commission acts.<sup>143</sup>

One of the adopted regulations, section 46.102, requires an institutional review<sup>144</sup> parallel to that established in the *Institutional Guide* and has the same unwarranted result: Only if the local Institutional Review Board determines that a subject is "at risk" do the regulations require further inquiry into the methods by which the investigator has provided for the rights and welfare of the subjects and for legally effective informed consent. While a weighing of risks and benefits is clearly applicable only if the subject actually is placed at risk, it is never inappropriate to examine an experiment for its potential benefits to society or to the individual. Furthermore, risk to subjects should not be the basis for limiting the number of subjects who are to be protected against unconsented activities or whose rights and welfare require safeguarding. Once an Institutional Review Board commences its inquiry, it should continue to oversee the experimental procedure to safeguard the subject's legal rights as well as medical well-being.<sup>145</sup> Quite possibly, the regulations define "subject at risk" so broadly that in practice

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142. Additionally, the Commission is to develop and recommend (1) sanctions to be applied if Review Boards fail to conform to federal policy; (2) compensation mechanisms for individuals and families injured by participation in experiments supervised by HEW; and (3) mechanisms to broaden the scope of its authority. *Id.*

It is the Committee's intent to work towards a day when all human subjects of biomedical or behavioral research programs, demonstrations, and activities are protected by the policies and procedures established by the Commission.

The Committee wishes to make it clear that the policies established by the Commission shall take precedence over existing DHEW policies governing biomedical and behavioral research involving human subjects. The Committee believes it is important to establish a single standard . . . .

S. Rep. No. 381, 93d Cong., 1st Sess. 29 (1974).

143. See notes 119-26 *supra* and accompanying text.

144. 45 C.F.R. § 46.102(b) (1975) states:

This review shall determine whether these subjects will be placed at risk, and, if risk is involved, whether:

(1) The risks to the subject are so outweighed by the sum of the benefit to the subject and the importance of the knowledge to be gained as to warrant a decision to allow the subject to accept these risks;

(2) The rights and welfare of any such subjects will be adequately protected; and

(3) Legally effective informed consent will be obtained by adequate and appropriate methods in accordance with the provisions of this part.

145. 45 C.F.R. § 46.102(d) (1975) provides:

Where the Board finds risk is involved under paragraph (b) of this section, it shall review the conduct of the activity at timely intervals.

Practicalities, however, may limit the Board's participation to reviewing periodic reports. At that, paperwork may prove ultimately unmanageable.

Institutional Review Boards may routinely find risk and inquire into protections provided for potential subjects in virtually every case. The extent of the review thus depends upon the scope of the phrase "subject at risk."

Any individual is "at risk" under section 46.103(b) if he "may be exposed to the possibility of injury,<sup>146</sup> including physical, psychological or social<sup>147</sup> injury" as a result of participation in certain kinds of activities.<sup>148</sup> The *Institutional Guide* defined "harm" to include, besides the obvious possibility of "a potentially harmful altered physical state," the possibility of "subjection to deceit, public embarrassment, and humiliation."<sup>149</sup> Even political science or sociology projects that provide no immediate physical threat may involve

varying degrees of discomfort, harassment, invasion of privacy, or may constitute a threat to the subject's dignity through the imposition of demeaning or dehumanizing conditions.<sup>150</sup>

A third kind of risk, described as "psychological, sociological, or legal," may arise when organs, tissues, or body fluids are obtained unethically or used inappropriately.<sup>151</sup> It is difficult to imagine what, other than an entirely routine therapeutic treatment, would constitute a no-risk experiment under the *Institutional Guide* explanation.<sup>152</sup>

146. The original word was "harm." INSTITUTIONAL GUIDE 2. "Injury" was deemed more "legal." 39 Fed. Reg. 18941 (1974).

147. The original word was "sociological." INSTITUTIONAL GUIDE 2. The term "social" was adopted in response to criticism that "sociological harm" was meaningless. 39 Fed. Reg. 18914 (1974).

148. 45 C.F.R. § 46.103(b) (1975) states:

"Subject at risk" means any individual who may be exposed to the possibility of injury, including physical, psychological, or social injury, as a consequence of participation as a subject in any research, development, or related activity which departs from the application of those established and accepted methods necessary to meet his needs, or which increases the ordinary risks of daily life, including the recognized risks inherent in a chosen occupation or field of service.

The ordinary therapeutic relationship between doctor and patient is thus excluded by definition.

149. INSTITUTIONAL GUIDE 2. For example, a psychology experiment on the effect of peer pressure on perception might prove embarrassing to a subject.

150. *Id.* at 2, 3.

151. *Id.* at 3. For example, if an accident victim's heart were donated for training purposes, its use in an experimental transplant could result in psychological injury to the donor's family.

152. Even therapy must be established and accepted, and meet the needs of the patient. See note 113 *supra* and accompanying text. It has been suggested that an anonymous telephone poll asking innocuous questions might fall within the scope of the regu-

The adopted regulations evince no intention to depart from the previous policy of defining risk in an all-encompassing manner. The remainder of section 46.103(b) injects a degree of objectivity into the previous definition of "subject at risk." Missing is the admission that such a determination "is a matter of the application of common sense and sound professional judgment."<sup>153</sup> In its place is a modification of the activities that place a subject "at risk": those that increase "the ordinary risks of daily life, including the recognized risks inherent in a chosen occupation or field of service."<sup>154</sup> The change in language is unlikely to bring about any alteration of the Review Boards' perceptions of risk, however, particularly because the latter half of the definition creates ambiguity rather than clarity. It is unclear, for example, whether the regulation refers to risk in terms of kind or degree.<sup>155</sup>

The regulations also fail to provide a method by which Boards are to ascertain "benefit to the subject and the importance of the knowledge to be gained"<sup>156</sup> and then weigh the benefit against the risk previously defined. Unanswered are questions such as how direct and imminent a benefit must be before it outweighs a substantial risk; whether the study must benefit the patient qua patient or whether the benefit may be to the patient in his role as a member of society; or how important the knowledge must be before individuals may be permitted to participate in an experiment that subjects them to risk. The foregoing are questions, not of professional judgment, but of community values. It is appropriate, therefore, to leave them to the discretion of a local Review Board so long as an initial attempt is made to agree upon ethical principles underlying the decision, and the Board includes individuals of varied backgrounds who are representative of the community. The regulations do provide that, because Review Boards must evaluate proposals in terms of "organizational commitments and regulations, applicable law, standards of professional conduct and practice, and commu-

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lations but beyond the concept of risk. Such a survey, however, could result in an invasion of the subjects' privacy if their anonymity were violated.

153. INSTITUTIONAL GUIDE 2.

154. 45 C.F.R. § 46.103(b) (1975).

155. The regulation instructs the local review committee to consider "the recognized risks inherent in a chosen occupation . . . ." However, an experiment too dangerous for participation by a bookkeeper would hardly be acceptable if military personnel were recruited as subjects. The language is probably intended to permit the Review Board to add additional protections for those subjects presumed to have little sophistication in the area. Thus, clinic patients would require more protection than physicians.

156. 45 C.F.R. § 46.102(b)(1) (1975).

nity attitudes," they must include "persons whose concerns are in these areas."<sup>157</sup> HEW provided little additional guidance for the Review Boards' substantive evaluation of proposals, relying instead heavily on the good faith of the members.<sup>158</sup>

Review by such a committee may be satisfactory from the community point of view, but institutions may find it difficult to recruit community members having the necessary expertise and time to devote to initial and continuing review. The problem is compounded when research involves any of the special subjects covered by the proposed rules. The proposed rules, concerned specifically with problems of consent, require an additional committee to oversee the selection of subjects, the obtaining of their voluntary and informed consent, and the continuation of consenting participation.<sup>159</sup> For the consent committee to be approved by the Secretary, it must include individuals unaffiliated with the institution and members who are not themselves engaged in experimentation with human subjects. Moreover, the members should be "competent to deal with the medical, legal, social and ethical issues involved . . ."<sup>160</sup> Again, this requirement imposes a severe burden on many institutions, particularly if the "unaffiliated" requirement is interpreted to mean that the members must serve without compensation. An HEW interpretive memorandum sent to grantee institutions, however, permits institutions to compensate and insure such members.<sup>161</sup>

In addition to the limits implicit in the creation of a committee to monitor consent, the proposed rules severely restrict the range of permissible experimentation when institutionalized mentally disabled persons are selected as the subject population. Proposed section 46.504 stipulates absolutely that as a condition precedent to any participation by an institutionalized mentally disabled individual, the proposed activity must be "related to the etiology, pathogenesis, prevention, diagnosis, or treatment of mental disability or the management, training, or rehabili-

157. 45 C.F.R. § 46.106(b)(1) (1975).

158. It is hoped that the National Committee authorized by The National Research Act will provide the necessary guidance. See note 142 *supra* and accompanying text.

159. 39 Fed. Reg. 30656, § 46.506(a) (1974).

160. 39 Fed. Reg. 30656, § 46.506(b) (1974).

161. Memorandum for Director, Office for Protection from Research Risks, Office of the Director, NIH, DHEW to Grantee and Contractor Research Officers with General Assurances, May 22, 1975.

Unaffiliated members may not "have a continuing financial dependence on the institution . . . [be] dependent on the institution for facilities, or [be] trainees, students, residents or interns dependent on the institution for admission." *Id.*

tation of the mentally disabled," and must seek "information which cannot be obtained from subjects who are not institutionalized mentally disabled."<sup>162</sup> Thus, regardless of a potential subject's capacity to make an informed decision about his participation in an experiment, he is denied the opportunity to consent unless the experiment bears an immediate relation to his mental disability. The language of the section is so confining in this respect that several investigators have objected lest research into the basic psychological processes be prohibited by the final rulemaking.<sup>163</sup> The second restriction has similarly been criticized for its overly rigid approach.<sup>164</sup> Literally interpreted, the provision would prevent virtually all research on institutionalized mentally disabled individuals, and would do so at the expense of the noninstitutionalized, who are protected by the less restrictive adopted section 46.102.

Proposed section 46.504 also imposes strict consent requirements. Legally effective consent must be secured from the individual or, if the individual is incompetent, from his legal representative. Moreover, if the individual is able to understand what is proposed and to express an opinion as to his participation, his assent must be obtained.<sup>165</sup> Although section 46.506 requires a separate consent committee to oversee this process, proposed section 46.505 requires the Institutional Review Board to make certain determinations regarding consent. One such determination is that experimenters offer "no undue inducements to

162. 39 Fed. Reg. 30655 (1974).

163. While there can be no guarantee that "pure" research will result in advances in the diagnosis and treatment of mental disabilities, it is unsafe to assume at the outset that it will not. . . .

Letter from Mary Henley to D.T. Chalkley, Nov. 13, 1974; see letter from William E. Fann, M.D. to D.T. Chalkley, Nov. 19, 1974; letter from Gerald A. Whitmarsh, Ph.D. to D.T. Chalkley, Oct. 29, 1974.

164. Letter from Charles C. Goodman, M.D. to D.T. Chalkley, Nov. 7, 1974; letter from Seymour S. Kety, M.D. to D.T. Chalkley, Nov. 13, 1974; letter from M. Brewster Smith to D.T. Chalkley, Nov. 19, 1974.

165. 39 Fed. Reg. 30655-56, § 46.504(b) and (c) (1974) require:

(b) The individual's legally effective informed consent to participation in the activity or, where the individual is legally incompetent, the informed consent of a representative with legal authority so to consent on behalf of the individual has been obtained; and

(c) The individual's assent to such participation has also been secured, when in the judgment of the consent committee he or she has sufficient mental capacity to understand what is proposed and to express an opinion as to his or her participation.

It is important to note that the regulations do not equate institutionalization with incompetency, and carefully distinguish between legal capacity to *consent* and ability to understandingly *assent*. See notes 56-58 and accompanying text *supra*.

participation" in an activity.<sup>166</sup> In light of the dismal conditions presently existing in some institutions,<sup>167</sup> any experiment that requires standard, much less enriched, diet, surroundings, or medical care could be found to offer "undue inducements to participation."<sup>168</sup> All positive reinforcement might also be precluded.<sup>169</sup>

## VI. CONCLUSION

In a civilized society committed to medical and scientific progress, reasonable regulation of experimentation is a necessity. Present HEW rule-making does, and future developments in response to recommendations by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research will, attempt regulation at a national level through the mechanism of local Institutional Review Boards. This review focuses upon three problem areas: the rights and welfare of subjects; informed consent; and risk-benefit ratios. Proposed regulations will provide further protections in each of the areas for specified subjects. Although the restrictions of subpart E concerning the institutionalized mentally disabled are to be read as additions to those imposed generally in the previously adopted subpart A, the limitations in subpart E are uniformly more severe. The range of possible experimental activities, the process of obtaining informed consent, and the scope of local review all impose heavy burdens on the experimenter. If interpreted without sound judgment, the proposed regulations may well cripple research in the mental health field, much to the detriment of those whom HEW tries most vigorously to protect.

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166. 39 Fed. Reg. 30656, § 46.505(2) (1974).

167. *See, e.g.*, *New York State Ass'n for Retarded Children, Inc. v. Rockefeller*, 357 F. Supp. 752 (E.D.N.Y. 1973) (children entitled to at least the same physical comforts and protections as prisoners); *Wyatt v. Stickney*, 344 F. Supp. 373 (M.D. Ala. 1972) (treatment program failed to provide humane psychological and physical environment). *But see* letter from Jonathan O. Cole, M.D., to D.T. Chalkley, Oct. 23, 1974:

I find the general tone of sub part E to be anachronistic. The fantasy of hordes of deprived chronic psychiatric patients languishing on back wards who may be seduced into research by being offered better food and better living quarters permeates the whole section. Such patients barely exist any more.

168. Letter from Seymour S. Kety, M.D., to D.T. Chalkley, Nov. 13, 1974.

169. Letter from Mary Alice White, Ph.D., to D.T. Chalkley, Oct. 10, 1974. This possibility points up the need for sound discretion in the interpretation of the proposed regulations.