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INSTITUTIONAL REVIEW BOARDS AND PUBLIC HEALTH RESEARCH: AN ANALYSIS

L. Lynn Hogue*

A flexible policy is essential. Research, development, and the reduction to practice of new ideas are not carried out in a practical, ethical, or legal vacuum. The public interest obviously would not be served by an inflexible approach to what can or should be done. Ultimately, the decisions required . . . must depend upon the common sense and sound professional judgment of reasonable men.¹

D. T. Chalkley, Ph.D.

Introduction

Experimental medical procedures have been subjected to litigation,² numerous studies,³ and congressional hearings investigating abuses,⁴ as has human experimentation in educational⁵ and psy-

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At this writing the National Commission was in the process of debating successive drafts of IRB Recommendations. To the extent possible under publishing deadlines, this article will consider the latest position taken by the Commission with respect to the implementation of DHEW regulations on the protection of human subjects.

1. U.S. Dep't of Health, Educ., and Welfare, *The Institutional Guide to DHEW Policy on Protection of Human Subjects*, iii (1971) [hereinafter cited as *Institutional Guide*].

2. *E.g.*, *Hyman v. Jewish Chronic Disease Hosp.*, 21 App. Div. 2d 495, 251 N.Y.S.2d 818 (1964), *rev'd*, 15 N.Y.2d 317, 206 N.E.2d 338, 258 N.Y.S.2d 397 (1965) (hypodermic injection of cancer cells into 22 human patients).

3. *E.g.*, H. Beecher, *Research and the Individual* (1970); *Biomedical Ethics and the Law* (J. Huber & R. Almeder eds. 1976) [hereinafter cited as *Biomedical Ethics*]; *Experimentation with Human Subjects* (P. Freund ed. 1970); C. Fred, *Medical Experimentation: Personal Integrity and Social Policy* (1974); N. Hershey & R. Miller, *Human Experimentation and the Law* (1976) [hereinafter cited as *Hershey & Miller*]; J. Katz, *Experimentation with Human Beings* (1972); Houlgate, *Rights, Health, and Mental Disease*, 22 Wayne L. Rev. 87 (1975); Ladimer, *Ethical and Legal Aspects of Medical Research on Human Beings*, 3 J. Pub. L. 467 (1954); Mullen, *Human Experimentation Regulations of HEW Bar Georgia Medicaid Cutbacks*, 10 Clearinghouse Rev. 259 (1976); *Viewpoints on Behavioral Issues in Closed Institutions*, 17 Ariz. L. Rev. 1 (1975); Note, *Medical Experiment Insurance*, 70 Colum. L. Rev. 965 (1970); Note, *Experimentation on Human Beings*, 20 Stan. L. Rev. 99 (1967); Comment, *Non-therapeutic Medical Research Involving Human Subjects*, 24 Syracuse L. Rev. 1067 (1973).

4. *E.g.*, *Hearings on Quality of Health Care—Human Experimentation before the Senate Comm. on Labor and Public Welfare*, S. Rep. No. 381, 93d Cong., 2d Sess., reprinted in [1974] U.S. Code Cong. & Ad. News 3634, 3638 [hereinafter cited as *Hearings*].

chological⁶ research. This article explores another area of nonmedical, experimental research on human subjects—public health research⁷—and suggests a proper analytic framework for those concerned with the protection of human subjects of such research. It is assumed that institutional review by boards designed to prevent abuses in experimental, therapeutic⁸ medical research can and does

5. E.g., DuVal, *Educational Research and the Protection of Human Subjects*, 1977 Am.

B. Foundation Research J. 477, 519:

Historically the emphasis in the regulation of research for the protection of subjects has been in the biomedical context. The nature of harm that students and teachers may sustain as a consequence of their participation in educational research differs markedly from, and on the whole is less dramatic than, that which may arise from biomedical research. Educational research does not present the risk of physical injury that is often inherent in biomedical research. Educational research may result in psychological stress and may invade the privacy interests of teachers and students. But while both the intentional infliction of psychological harm and the invasion of privacy are actionable, the likelihood that substantial damages will be imposed is less than in biomedical research.

6. Ad Hoc Comm. on Ethical Standards in Psychological Research, Ethical Principles in the Conduct of Research with Human Participants (1973); London, *Experiments on Humans: Where To Draw the Line*, Psychology Today, Nov. 1977, at 20. E.g., Ethical and Legal Issues of Social Experimentation (A. Rivlin & P. Timpane eds. 1975); Social Research in Conflict with Law and Ethics (P. Negelski ed. 1976).

7. A fundamental characteristic differentiating "public health" from other health and medical disciplines is its corporate focus or emphasis on more than just individuals. This concept has been described as follows:

In scientific public health, we no longer treat the individual—the segment of the community—but the total body politic—mental, physical, social, and economic. We no longer treat individuals with communicable diseases, but we prevent, control, or eradicate the disease in the body politic. The total patient is our responsibility [i.e., the community], and not the individuals who are a part of it.

McGavran, *What is Public Health?* 44 Canadian J. Pub. Health 441, 444 (1953). "*Public Health is the scientific diagnosis and treatment of the body politic or community.*" *Id.* at 447 (emphasis in original).

As will be seen, this corporate or community focus has significant legal implication since the "risk" to which study populations may be exposed in studies involving community measurements, demographic characteristics, etc., is substantially attenuated when compared with that inherent in medical research. The traditional assumption, however, is that all research is therapeutic and aimed at treatment of individuals: "Most biomedical investigators are . . . interested in taking care of patients and making them well." Barber, *The Ethics of Experimentation With Human Subjects*, Scientific Am., Feb. 1976, at 25, 30. No more articulate expression of the erroneous assumption that all research is necessarily therapeutic could be found. It is to assist in righting this notion and urging a proper understanding of institutional review for nontherapeutic research that this article was written.

8. *Therapeutic research, nontherapeutic research.*

The Commission recognizes problems with employing the terms "therapeutic" and "nontherapeutic" research, notwithstanding their common usage, because they may convey a misleading impression. Research refers to a class of activities designed to develop generalizable new knowledge. Such activities are often engaged in to learn something about practices designed for the therapy of the individual. Such research is often called "therapeutic" research; however, the research is not solely for the therapy of the individual. In order to do research, additional interven-

unduly restrict public health researchers whose projects do not involve the dangers to subjects that institutional review was designed to mitigate or avoid.⁹

The current requirements for institutional review¹⁰ are imposed by the United States Department of Health, Education, and Welfare (DHEW) on institutions administering studies involving biomedical or behavioral research on human subjects under authority of a provision of title II of the National Research Act of 1974.¹¹ The necessity for some regulation in this area is apparent from hearings conducted by the Subcommittee on Health of the Senate Committee on Labor and Public Welfare. The concerns reflected in testimony before the Subcommittee shaped both the statutory requirement for institutional review boards (IRBs) and the content of subsequent regulatory guidelines.¹²

The Subcommittee heard accounts of the unapproved use of drugs approved by the Food and Drug Administration (FDA) for other uses, other types of nonpharmaceutical medical experiments, and medical experiments and treatment without informed consent. In each of these instances, patients or subjects were not fully informed about the nature of the experiments in which they were involved or, in some instances, were not told that they were involved in a medical experiment at all. Specific instances presented in subcommittee testimony included the following: (1) the use of Depo-

tions over and above those necessary for therapy may need to be done, e.g., randomization, blood drawing, catheterization; these interventions may not be "therapeutic" for the individual. Some of these interventions may themselves present risk to the individual—risk unrelated to the therapy of the subject.

Nat'l Comm'n for the Protection of Human Subjects of Biomedical and Behavioral Research, *Research Involving Prisoners* (1976) [hereinafter cited as National Commission].

The special considerations applicable to therapeutic research are further apparent in the following caveat—part of Nat'l Comm'n for the Protection of Human Subjects of Biomedical and Behavioral Research, *IRB Recommendations, Recommendation (3)(D), Comment (D)* at 16 (Draft March 3, 1978) [hereinafter cited as Commission Draft]: "The involvement of a physician or therapist as an investigator may have significant advantages for patients and make available to them new forms of therapy. However, research interests may compromise the therapist's sound judgments regarding therapeutic goals."

9. "In recent years . . . widespread societal concern for privacy and confidentiality, often manifest in confusing or ambiguous regulations, has made many types of epidemiologic and other medical investigation increasingly difficult to conduct and, in fact, now threatens to make many such studies virtually impossible." Gordis, Gold, & Seltser, *Privacy Protection in Epidemiologic and Medical Research: A Challenge and a Responsibility*, 105 Am. J. of Epidemiology 163, 163 (1977).

10. The development of institutional review is surveyed in 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 (1975).

11. 42 U.S.C. § 2891-3(a) (Supp. V 1975).

12. 45 C.F.R. §§ 46.101-.301 (1976); *Hearings*, *supra* note 4, at 3638.

Provera, a drug approved by the FDA for the treatment of endometrial cancer and endometriosis, as a three-month injectable contraceptive given to more than 1500 women under the Tennessee Maternal Health Family Planning Program without FDA approval and without informing the women involved;¹³ (2) use of diethylstilbestrol (DES) as a post-coital contraceptive at several universities, although DES was not approved for this use;¹⁴ (3) psychosurgery on patients in mental hospitals;¹⁵ (4) use of a "supercoil" experimental intrauterine device developed by a nonphysician and implanted in several out-of-state women by a physician;¹⁶ (5) the Tuskegee Syphilis Study;¹⁷ (6) biomedical research in prisons and research on the effects of the biomedical research testing program on the rest of the prison social structure;¹⁸ (7) the sterilization of minor welfare recipients without their parents' informed consent.¹⁹ The Subcommittee also learned that, in some instances, research was not scrutinized by the researcher's scientific or professional peers and that some physician researchers simply conducted biomedical research as an adjunct to their medical practices.

Several bills were introduced in Congress to correct these abuses.²⁰ One approach was to establish a permanent national commission for the protection of human subjects that would have power to investigate and report on human subjects research; the commission would establish guidelines for IRBs and publish and distribute the decisions made by IRBs. Congress did not fully adopt this approach in the legislation finally enacted. It was also proposed, but rejected, that IRBs would be required to have a two-part structure: (1) a subcommittee that would review the scientific merits of research protocols submitted to it; and (2) a subcommittee that would "focus primarily on ensuring that the individual subjects of biomedical and behavioral research . . . are as well informed about the nature of the research as possible and that their rights are protected to the maximum extent."²¹

What emerged out of this legislative concern over abuses in experimental biomedical and behavioral research was a law establishing a temporary National Commission for the Protection of

13. *Hearings, supra* note 4, at 3638.

14. *Id.* at 3639.

15. *Id.* at 3640.

16. *Id.* at 3642.

17. *Id.*

18. *Id.*

19. *Id.* at 3645.

20. See Ratnoff, *supra* note 10, at 517 n.280 for list.

21. *Hearings, supra* note 4, at 3656.

Human Subjects of Biomedical and Behavioral Research (National Commission), and a requirement that DHEW mandate institutional review by IRBs and issue guidelines to govern them.²² The guidelines on "Protection of Human Subjects," published in final form in the *Federal Register* in 1975, reflect many of the concerns already discussed that were before Congress.²³ For example, an elaborate definition of "informed consent" was set out to eliminate the abuses resulting from widely differing interpretations of that term as it was used by researchers.²⁴

1. *Institutional Review Board Regulations and the Review Process*

a. *Scope*

The regulations on the protection of human subjects are applicable to all DHEW grants and contracts supporting research, development, and related activities in which human subjects are involved. This includes nonmedical, educational,²⁵ and other research. Special protection is extended to pregnant women and fetuses under other parts of the regulations,²⁶ which are beyond the scope of this article.

22. 42 U.S.C. § 2891-3(a) (Supp. V 1975).

23. 40 Fed. Reg. 11, 854 (1975), 45 C.F.R. §§ 46.101-.301 (1976).

24. The range in practice in securing "informed consent" is reflected in the following episodes excerpted from the hearings of the Senate Committee on Labor and Public Welfare preceding the legislation and regulations on human subjects research:

DepoProvera research (use of FDA-approved drug for an unapproved purpose): "Anna Burgess, one of the women who received [DepoProvera as an injectable contraceptive] testified that she was never informed of the potential side effects, never signed a consent form, and experienced a significant degree of discomfort after taking the drug. Dr. Kase and Ms. Greenberger reported on the results of a field investigation in which six women in Cumberland County, Tennessee[,] including Miss Burgess, were interviewed about the use of DepoProvera. Dr. Kase concluded that informed consent was not obtained in any of the six cases, no attempt was made to achieve patient awareness, and the potential short and long term hazards of the drug were not discussed."

Hearings, supra note 4, at 3638-39.

The following position of the American Medical Association is analogous:

Dr. Barclay, testifying on behalf of the American Medical Association, said that the final responsibility for the treatment of patients rests with the individual physician, and that it was proper for him to have the right to use an unapproved drug or to perform experimental surgery if that was, in his, the physician's opinion in the best interest of the patient.

Id. at 3643.

On "informed consent" to medical treatment, as the term is used in its more conventional sense, see Schneyer, *Informed Consent and the Danger of Bias in the Formation of Medical Disclosure Practices*, 1976 Wis. L. Rev. 124; Waltz & Scheuneman, *Informed Consent to Therapy*, 64 Nw. U.L. Rev. 628 (1970).

25. See DuVal, *supra* note 5.

26. 45 C.F.R. §§ 46.102(c), .201-.211 (1976). IRBs' additional responsibilities are found in 45 C.F.R. § 46.205 (1976).

b. *Policy*

The regulations are designed to safeguard the rights and welfare of subjects "at risk" in activities supported by DHEW contracts and grants.

c. *Procedure*

IRBs are to review research proposals and determine whether subjects will be placed "at risk." If they will be, the IRB is then further to determine (1) whether "[t]he 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) whether "[t]he rights and welfare of such subjects will be adequately protected"; and (3) whether "[l]egally effective informed consent²⁷ will be obtained by adequate and appropriate methods in accordance with the provisions of the regulations."²⁸

The regulations also provide for the periodic review of projects involving subjects "at risk."²⁹ There is also a requirement that projects not initially involving human subjects must be brought under review by the IRB if such subjects are later involved.³⁰

d. *Sanctions*

The responsibility for enforcing these safeguards to subjects belongs to the institution that receives the funding or is accountable to DHEW for it.³¹ Institutions must assure DHEW that review will be instituted.³² Unapproved studies are not eligible for DHEW funding.³³ Negative determinations by an IRB are the primary sanction

27. "As originally proposed the regulation did not contain the words 'legally effective.' . . . The insertion of the phrase was suggested in comments on the proposed rule. . . . No explanation of the significance of the addition was given." DuVal, *supra* note 5, at 509 n.121.

28. 45 C.F.R. § 46.102 (1976).

29. *Id.* § 46.102(d).

30. *Id.* § 46.114.

31. *Id.* § 46.102(a).

32. *Id.* § 46.104.

33. Failure to conform to the agreement between an institution and DHEW, as set out in the institution's assurance to DHEW, could lead to a loss of research funding by DHEW. With respect to sanctions, the Commission Draft, *supra* note 8, at 9, has proposed the following:

Recommendation (2)(A) Federal law should be enacted or amended to authorize the secretary of Health, Education, and Welfare to carry out the following duties:

. . . .

(ii) Compliance activities, including site visits and audits of institutional

against an investigator, and a negative IRB determination can only be reversed by the IRB. IRB approval does not obligate an institution to a particular research project if institutional administrators disapprove, but the findings of the IRB cannot be rescinded administratively if they are negative.³⁴

Since DHEW research is funded by the government and presumably serves a public interest, it could be argued that the government should assume responsibility for the programs it funds and scrutinize programs for the protection of human subjects. The bureaucratization this approach would entail has precluded adoption or even serious consideration of it.³⁵

The government could also protect human subjects by focusing on bad results and providing compensation for them.³⁶ This could be done through an insurance pool built up by the profits of new research, thereby letting the technical benefits of research bear the burdens of their discovery, or a no-fault system like workers' compensation for human subjects injured through research. As a less comprehensive remedy, the Federal Tort Claims Act³⁷ could be extended to cover subjects injured through negligence or wrongful con-

review board records, to examine the performance of the boards and their fulfillment of institutional assurances and regulatory requirements

Comment: . . .

Site visits, audits of IRB records, and other compliance activities should be conducted routinely to assure continuing quality control of the performance of IRBs. The compliance effort should be aimed at educating, improving performance of IRBs and providing needed advice. Where necessary, however, failure by investigators, institutions or IRBs to meet their responsibilities should be subject to sanctions ranging from warnings to loss of IRB accreditation and consequent ineligibility to receive federal funds for research involving human subjects or refusal by a regulatory agency to accept data.

34. 45 C.F.R. § 46.118 (1976).

35. For instance, even the essentially aggrandizing recommendations of the National Commission eschew national review in favor of local IRB screening as follows:

The Commission believes that the rights of the subjects should be protected by local review committees operating pursuant to federal regulation and located in institutions or other entities where research involving human subjects is conducted. Compared to the possible alternatives of a regional or national review process, local committees have the advantage of greater familiarity with the actual conditions surrounding the conduct of research . . . [and] can work in cooperation with local investigators to assure that [subjects are protected] and . . . that [policies are fairly applied to investigators]

Commission Draft, *supra* note 8, at 1-2.

36. For discussion of an analogous program designed to absorb catastrophic costs of medical care, see Havighurst, Blumstein & Bovbjerg, *Strategies in Underwriting the Costs of Catastrophic Disease*, 40 L. & Contemp. Prob. 122, 127-34 (1976).

37. 28 U.S.C. §§ 1346, 1402, 1504, 2110, 2401, 2402, 2411, 2412, 2671-2680 (1970). See W. Prosser, *Law of Torts* § 131, at 972 (4th ed. 1971).

duct in government-funded research programs, including projects conducted by others under a contract or grant. Compensation mechanisms would have the advantage of assuming the cost of misadventures in such research as a public cost of advancing knowledge while at the same time fostering research.

e. Membership and Organization

The membership and organization of the IRBs are controlled by federal regulation.³⁸ A minimum of five persons is required, and a quorum for the IRB is a majority of its members. The regulations require that not all members of the board come from within the institution itself³⁹ or from any single professional group.⁴⁰ A board member is prohibited from participating in a review of his own project or one in which he is involved, except to the extent of providing information to the board.⁴¹ Documentation of the training and experience of board members is required.⁴²

An underlying assumption of the regulations is that IRB members must be competent to determine when a human subject is placed "at risk" and, when "subjects at risk" are identified, to be able to weigh intelligently the risk to the subject against the benefits to him and to society through the knowledge to be gained by the research. IRB members must also be knowledgeable enough to know whether the welfare of the subject will be protected and whether legally effective informed consent will be obtained. One proposal considered by Congress but rejected, as was noted earlier, was to provide for a two-part IRB: one subpart of the board to weigh the scientific merits of the proposed research protocols and the other to provide for the protection of the human subjects "at risk."⁴³ Although Congress did not include this two-part IRB in the final language of the National Research Act of 1974, elements of both functions are to be found in the present system. They are not clearly delineated, however. Implicit in weighing the risks and benefits of a given project is determining whether the research is worth doing from a scientific point of view and also whether a particular project is a good way in which to gain the information sought.⁴⁴

38. 45 C.F.R. § 46.106(b) (1976). See also Hershey & Miller, *supra* note 3, at 79-85.

39. 45 C.F.R. § 46.106(b)(4) (1976). Commission Draft, *supra* note 8, at 14, suggests that an institution provide remuneration to nonemployees serving on an IRB.

40. 45 C.F.R. § 46.106(b)(5) (1976).

41. *Id.* § 46.106(b)(3).

42. *Id.* § 46.106(b)(2).

43. *Hearings, supra* note 4, at 3656.

44. Proposals to define further the role of the IRB in exercising scientific oversight have been advanced. *E.g.*, Commission Draft, *supra* note 8, at 17 states as follows:

The congressional choice to compel institutions to provide protection, rather than assuming that responsibility within DHEW, has forced researchers' peers in an IRB to undertake a fairly complex evaluative task without much legal guidance. Once an IRB determines that a subject is "at risk" it must consider (1) whether "[t]he 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) whether "[t]he rights and welfare of any such subjects will be adequately protected"; and (3) whether "[l]egally effective informed consent will be obtained by adequate and appropriate methods. . . ." ⁴⁵

The procedural steps in arriving at the issue of risk are well illustrated by *Crane v. Mathews*,⁴⁶ wherein the State of Georgia secured permission from DHEW to impose co-payment requirements on its Medicaid recipients⁴⁷ in an effort to reduce steadily

Recommendation (4) The Secretary of Health, Education and Welfare should require by regulation that all research involving human subjects that is subject to federal regulation shall be reviewed by an institutional review board and that the approval of such research shall be based upon affirmative determinations by the board that:

(a) The research methods are appropriate to the objectives of the research and the field of study.

The effect of this recommendation would be to compel a double peer review of the scientific protocols of many projects. See 42 U.S.C. § 2891-4 (Supp. V 1975). Peer review has come under attack recently as unduly limiting research by channeling it in directions already sanctioned by scientific consensus. One possible effect of this limitation is to foreclose new ideas and new technologies by denying them funding and thereby perpetuating the commonplace. See Rosenbaum, *Cancer Research: Ordeal By Peers*, New Times, Feb. 20, 1978, at 10 (denial of continued funding to Dr. Raymond Damadian of the Biophysical Laboratory, S.U.N.Y. Brooklyn for continued research on the use of nuclear magnetic resonance (NMR) for the detection of malignant tissue); Damadian, Minkoff, Golfsmith, Stanford, & Koutcher, *Field Focusing Nuclear Magnetic Resonance (FONAR): Visualization of a Tumor in a Live Animal*, 194 Science 1430 (1976).

45. 45 C.F.R. § 46.102(b)(1)-(3) (1976). The adequacy and appropriateness of methods used to secure informed consent are described in detail at *id.* §§ 46.103(c)-.110.

46. 417 F. Supp. 532 (N.D. Ga. 1976). See also *Clay v. Martin*, 509 F.2d 109, 111-13 (2d Cir. 1975) (prisoner's pro se complaint was based on an experimental drug program in 1970 in which plaintiff suffered a serious heart attack after injection with Naltrexone; consent was based on physician's assurance that the dosage involved would be too small to cause harm).

47. Under the Medicaid portion of the Social Security Act, states instituting a Medicaid plan must do so in conformity with the Act and with the approval of the Secretary of DHEW. 42 U.S.C. § 1396 (1970). Assistance is required for individuals receiving grants under the Act's cash assistance program, the "categorically needy." *Id.* § 1396a(a)(10)(A). The Georgia program included only the categorically needy.

The Medicaid program includes both mandatory and optional services. *Id.* § 1396d(a)(1)-(17) (1970 & Supp. V 1975). Categorically needy recipients cannot be required to contribute to the costs of mandatory services, and any charges for optional services must be nominal in

rising Medicaid costs.⁴⁸ The project was approved as an experiment on "Recipient Cost Participation in Medicaid Reform" designed to test whether co-payment "would curtail overutilization in Georgia of 'marginally needed' health care."⁴⁹

An action brought by plaintiff Medicaid recipients in federal district court sought, among other things, a preliminary injunction against the imposition of co-payment requirements. The preliminary injunction was denied,⁵⁰ as was a motion by the Secretary of DHEW for summary judgment.⁵¹ Following a trial, the court found that the co-payment project was covered by the regulations for the protection of human subjects⁵² and required submission of the project to the state's IRB⁵³ for review:

The question . . . before the Court is: Are human subjects involved in the Georgia co-payment project in such a way as to trigger the provisions of 45 C.F.R. § 46? The Court need not determine whether the subjects are at risk; this is a determination to be made by the IRB, only after a determination is made that human subjects are involved.⁵⁴

Although the cutbacks in benefits were ostensibly justified as "experiments," they were in fact merely reductions which could be permitted under applicable Medicaid law only when characterized as "experimental."⁵⁵ The *Crane* court held that IRB review was

accordance with standards approved by the Secretary of DHEW and included as a part of the state's plan. See *Crane v. Mathews*, 417 F. Supp. 532, 536 (N.D. Ga. 1976).

48. It is clear that the Medicaid program has important cost considerations.

The incurring of excess costs with respect to one phase of the Medicaid program may very well mean a reduction of the program in another area. The public purse, both that of the state and even of the United States, is not absolutely unlimited. Accordingly, public officials must make some effort to provide the greatest good possible at the least possible costs.

Crane v. Mathews, 417 F. Supp. 532, 540 (N.D. Ga. 1976).

49. The Social Security Act, 42 U.S.C. § 301 (1970), provided for "experimental, pilot, or demonstration project[s] which, in the judgment of the Secretary [of DHEW are] likely to assist in promoting the objectives of [the public assistance program]." *Id.* § 1315. Such projects require a waiver by the Secretary. *Crane v. Mathews*, 417 F. Supp. 532, 536-37 (N.D. Ga. 1976); 42 U.S.C. § 1315(a) (1970). The *Crane* court held that projects approved under a § 1315 waiver were subject also to the regulations of the protection of human subjects, 45 C.F.R. §§ 46.101-.301 (1976). *Crane v. Mathews*, 417 F. Supp. 532, 545 (N.D. Ga. 1976).

50. *Crane v. Mathews*, 417 F. Supp. 532, 540 (N.D. Ga. 1976). The denial was predicated on plaintiff's failure to meet the tests of *Canal Auth. of Fla. v. Callaway*, 489 F.2d 567 (5th Cir. 1974).

51. *Crane v. Mathews*, 417 F. Supp. 532, 540 (N.D. Ga. 1976).

52. *Id.* at 545; 42 U.S.C. § 1315(b) (1970); 45 C.F.R. §§ 46.101-.301 (1976).

53. See *Crane v. Mathews*, 417 F. Supp. 532, 543 n.2 (N.D. Ga. 1976) (on the Georgia State IRB).

54. *Id.* at 544.

55. *Id.* at 536-37; 42 U.S.C. §§ 1315(a), 1396 (1970 & Supp. IV 1974); 45 C.F.R. §§ 46.101-.301 (1976).

required, but it did not address the definitions applicable in that review.⁵⁶ The court then denied a motion by the defendant to dismiss and granted plaintiff's motion for a permanent injunction to take effect only if certain conditions, one of which was submission of the project for IRB approval, were not met. According to plaintiff's attorney in *Crane*, the Georgia IRB "determined [on remand] that the 'human subjects' [identified by the court in the *Crane* case] were 'subjects at risk' and that potential benefits of the experiment were so outweighed by the risks that the project should be discontinued."⁵⁷ The experiment was accordingly ended July 30, 1976.⁵⁸ It should be noted that the result reached by the Georgia State IRB in *Crane* may have been compelled in part by the virtual impossibility of applying the protective safeguards required by the regulations, such as legally effective informed consent,⁵⁹ after subjects were found to be at risk. Since the co-payment requirement was imposed statewide,⁶⁰ securing informed consent would be difficult or impossible because few welfare recipients would voluntarily choose to make co-payments. An even more important factor in *Crane* was the use of the human subjects research regulations as a legal strategy to stave off a statewide reduction in Medicaid benefits. While the reduction was styled as an "experiment" by the State of Georgia and the cooperation of DHEW secured on that basis, the Medicaid reduction "experiment" was probably not the sort contemplated by the National Research Act of 1974,⁶¹ if the hearings preceding it are any guide.

56. The *Crane* court, which did not reach the issue of "risk," was solely concerned with the lack of definitions for "grants and contracts supporting research, development, and related activities" in 45 C.F.R. § 46.101(a) (1976), which it had to construe in *pari materia* with the scope of the § 1315 waiver and with "human subjects" in 45 C.F.R. § 46.101(a) (1976). *Crane v. Mathews*, 417 F. Supp. 532, 544 (N.D. Ga. 1976). Since "risk" was not before the court, its definition was worth only a passing footnote. *Id.* n.3, which does not clearly establish the definition of "risk."

57. Quoted in Mullen, *supra* note 3, at 260.

58. *Id.*

59. 45 C.F.R. § 46.102(b)(3) (1976); see also Mullen, *supra* note 3, at 260 n.7.

60. A blanket reduction in welfare benefits would entail some but not all of the procedural safeguards of *Goldberg v. Kelly*, 397 U.S. 254 (1970). See *Burr v. New Rochelle Mun. Housing Auth.*, 479 F.2d 1165, 1169 (2d Cir. 1973), in which the court held "that due process does not require an adversary hearing before a general rent increase or service charge can be imposed." See generally Friendly, "Some Kind of Hearing," 123 U. Pa. L. Rev. 1267 (1975).

61. 42 U.S.C. §§ 218, 241-2a, 282, 286a, 286b, 287b, 287d, 288a, 289c-1, 289g, 289k, 289l-1 to -3, 295f-2 to -3(b), 295f-3(q), 300a-7 (Supp. IV 1974). Cf. *Dodson v. Parham*, 427 F. Supp. 97 (N.D. Ga. 1977) (proposed restriction of list of drugs for Medicaid recipients for which reimbursement of pharmacists would be available).

2. *Defining and Determining Risk*

The determination of whether a human subject of a research project is "at risk" is the IRB's principal function, and it is central to research project approval. It is in this step that an IRB, particularly one in an institution doing public health research, has the greatest opportunity to avoid hampering its institution's research effort. Public health-related IRBs should weigh carefully how they understand and apply these guidelines.

The function of any IRB in determining subject risk can most appropriately be viewed as a two-step process. The initial inquiry is whether human subjects are involved in the research.⁶² If they are not, then review under these regulations proceeds no further. If they are, the next step is a determination of whether a subject of the research will be placed "at risk." This determination is crucial. If no human subjects are placed "at risk," the further requirements of the regulations are obviated.⁶³ "This review shall determine whether these subjects will be placed at risk, and if risk is involved,"⁶⁴ then the IRB must consider risk versus benefit, protection of the subject's rights, and the matter of consent, as previously mentioned. The form certifying that review has taken place⁶⁵ echoes this procedural view, for IRBs must certify for each project:

Human Subjects: Reviewed, Not at Risk.

Human Subjects: Reviewed, At Risk, Approved.

The words "at risk" have a special definition, supplied by the regulations themselves.⁶⁶

a. *Defining Risk to Subjects*

Under the DHEW regulations, a "subject at risk" is 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 ordi-*

62. "The regulations only apply if a determination is made that the project in question involves human subjects." *Crane v. Mathews*, 417 F. Supp. 532, 543, 547 (N.D. Ga. 1976).

63. 45 C.F.R. § 46.102(b) (1976). It is apparently the intent of Commission Draft, *supra* note 8, at 2-4, to extend review into the conduct of research involving human subjects who are not "at risk." Any such expansion of IRB authority should be viewed with caution by institutions that are seriously interested in innovative research.

64. 45 C.F.R. § 46.102(b) (1976).

65. *Id.* § 46.111(a).

66. *Id.* § 46.103(b).

*nary risks of daily life, including the recognized risks inherent in a chosen occupation or field of service.*⁶⁷

The definition clearly does not treat all risks as placing a subject "at risk." The inclusive category of "any individual . . . who may be exposed to the possibility of injury . . . as a subject in any research" is carefully limited by the two clauses beginning with "which" that follow it. Although it is possible to interpret the definition in a more expansive fashion (more restrictive to researchers), a construction stressing the language concerning "the possibility of injury" and viewing any subject as "at risk" who is so exposed should be rejected for public health research.

This is true because an IRB finding that a subject is "at risk" in turn mandates the use of DHEW-required procedural protections such as fully documented,⁶⁸ legally effective⁶⁹ informed consent⁷⁰ which includes (1) a fair explanation of the procedures to be followed and their purposes, including identification of any procedures which are experimental; (2) a description of any attendant discomforts and risks reasonably to be expected; (3) a description of any benefits reasonably to be expected; (4) a disclosure of any appropriate alternative procedures that might be advantageous for the subject; (5) an offer to answer any inquiries concerning the procedures; and (6) an instruction that the person is free to withdraw his consent and to discontinue participation in the project or activity at any time without prejudice to the subject. One option open to IRBs is to assume that all research on humans places them at risk. If the additional procedural requirements are imposed on all human research, then at least two positive results follow: (1) Subjects are extended maximum protection even against remote, highly contingent, or speculative risks. Pushed to an extreme, research might protect human subjects by reducing even ordinary dangers through an excess of caution exercised in the experimental environment. (2) Any possibility of error or liability for error by the IRB in the assessment of "risk," such as errors in applying the definition to the research protocol,⁷¹ is reduced to nil. This safe path also affects research by limiting it, by making it more costly, and, in some instances, by adversely affecting research protocols.

67. *Id.*

68. *Id.* § 46.110. See also Hershey & Miller, *supra* note 3, at 29.

69. See DuVal, *supra* note 5.

70. 45 C.F.R. § 46.103(c) (1976). Cf. Berger & Stallones, *Legal Liability and Epidemiological Research*, 106 J. of Epidemiology 177, 178 (1977) ("Determination of informed consent in epidemiologic studies is particularly difficult").

71. 45 C.F.R. § 46.102(b)(3). See also Mullen, *supra* note 3, at 260 n.7.

If all subjects are given the maximum procedural protection available under DHEW guidelines, then these subjects of any research would be extended the same protection as subjects of experimental, therapeutic, medical research. Put another way, a person asked simply to answer a questionnaire⁷² would be given the same protection as someone undergoing experimental cancer chemotherapy.

Under such constraints, some types of public health research are made more difficult, if not impossible, by procedures that require fully documented, legally effective informed consent of a type appropriate by and large only for medical research. An experiment, for example, may be spoiled if those in either the experimental or the control group are told that they are involved in an experiment in which their attitudes or preferences are being observed and evaluated. The fact that the subjects are aware of the experiment, its purposes, and the alternative paths of behavior may hopelessly prejudice the outcome of the experiment.

Another problem is that simple experiments, such as telephone surveys, may become pointless when subjected to rigid formal requirements of informed consent. Telephone surveys minimize the cost and effort required by personal contact; but if a rigid application of the "at risk" notion requires prior, documented, legally effective informed consent for a simple telephone interview, then the researcher might as well rely on the traditional interviewer who can take a consent form along or he may forego gathering the information altogether because of such a restrictive research climate.⁷³

At some point it becomes valid to inquire how important it is

72. Cf. Hershey & Miller, *supra* note 3, at 29:

Questionnaires raising issues that might be emotionally disturbing or might elicit potentially embarrassing information also place a subject at risk. Thus, an investigator should be seeking socially neutral information through methods that add no risk of physical or psychological injury before he requests a determination that subjects are not at risk.

The extreme or categorical position taken by Hershey & Miller apparently disregards the potential "risks" in the normal assaults of daily social intercourse. Consider these questions: "Haven't you had three martinis already?" "Didn't your first pregnancy end in a miscarriage?" "Have you ever had (an abortion, a vasectomy, venereal disease, tuberculosis, an ingrown toenail, a disturbing sexual experience, etc.)?" The potential for harm from blunt, nosey questions is always present but is taken in stride by most as part of the "ordinary risks of daily life." While the calculated effort on the part of an investigator to ask a blunt or socially embarrassing question might distinguish it from the chance inquiry at a social gathering, in fact the reply/response (if any) in an experimental context is less exposed to the chance of disclosure, embarrassment, or coercion than if the question is put at a social occasion.

73. Commission Draft, *supra* note 3, at 25-26, leaves some latitude for the conduct of simple surveys without consent formalities, but the force of these in freeing investigators will largely depend on the definition of "risk" adopted by the IRB.

to evaluate both innovations and long accepted notions about health and health care delivery involving human subjects. If any differentiation for experimental purposes is presumed to entail "risk," then society faces the unhappy prospect of permitting innovations without being able to evaluate them because disclosure to the control and acquisition of his consent will destroy the effectiveness of having a control. If research involving human subjects is desirable and even necessary, then the IRB can be seen as exercising a crucial role in the future of research because it can either facilitate or hamper research by its interpretation of the rules it applies. Some research, even though it involves humans, does not involve the risks inherent in novel biological or psychological manipulation or medical research of a therapeutic nature. In short, elaborate safeguards should not be required if research does not involve "risk."

b. Determining When Human Subjects Are Placed at Risk

If not every research project involving human subjects places them at risk, then it is necessary to distinguish between that research which does and that which does not involve risks. The Georgia IRB's finding that human subjects were "at risk" used a broader interpretation of "subject at risk" than one suggested by the situations before Congress when it imposed IRB review; Congress legislated in response to projects which departed from established treatment regimens, such as the use of FDA-approved drugs for unapproved purposes, psychosurgery, and other techniques of behavior manipulation.

It should be noted that the areas of concern addressed by the legislative hearings on the National Research Act of 1974 were the source of the examples of "risk" cited by DHEW Secretary David Mathews in a notice published in the *Federal Register*, "Secretary's Interpretation of 'Subject at Risk,'" ⁷⁴ issued in the midst of the *Crane* litigation. The Secretary's interpretation pointed out several examples of DHEW-funded, welfare-related research in which subjects were not considered by DHEW to be "at risk." It was not surprising that the instances cited in the Secretary's interpretation included projects designed to test methods for reducing welfare benefits and their attendant burden on the public fisc in some states. ⁷⁵

The examples cited by the Secretary of how DHEW interprets the definition of "subject at risk" in the context of the Medicaid

74. 41 Fed. Reg. 26,572-73 (1976).

75. *Crane v. Mathews*, 417 F. Supp. 532, 540 (N.D. Ga. 1976); 41 Fed. Reg. 26,572-73 (1976).

cutback program are, as will be seen, consistent with a careful reading of the regulations. They also offer public health researchers an opportunity to avoid problems resulting from unnecessary or inappropriate procedural requirements and to achieve greater flexibility in designing study protocols and appropriate protection for human subjects of public health research. The Medicaid experiments were as follows: (1) Some welfare recipients were to report their incomes more frequently than others for purposes of determining their eligibility for, or the level of, their welfare benefits. (2) Some, but not all, able-bodied welfare recipients were required to work as a condition of eligibility. (3) The level of welfare benefits (within prescribed boundaries) payable to some, but not all, similarly situated welfare beneficiaries was diminished. (4) Some, but not all, welfare recipients were required to make a co-payment toward the cost of governmentally-financed medical care (as in *Crane*).⁷⁶

In his interpretation, the Secretary urged that these four experiments

[did] not constitute burdens or effects of the nature that the regulations [for the protection of human subjects] are intended to encompass and, therefore, would not place the individuals subject to these burdens or effects "at risk" within the meaning of the regulation. In the context of the regulations, there would be no departure from the range of "established and accepted methods necessary to meet [the] needs [of the individual]" in these types of circumstances.⁷⁷

The standard used by the Secretary to measure a "departure" from the norm was "the average American in his daily life."⁷⁸ Since the average able-bodied American must work, it is no departure from the norm to require able-bodied welfare recipients to work, even though the norm for welfare recipients is not working. Similarly, income reporting, lowered incomes, and some payment for medical care⁷⁹ are not departures from normal experience. The Sec-

76. *Crane v. Mathews*, 417 F. Supp. 532 (N.D. Ga. 1976).

77. 41 Fed. Reg. 26,573 (1976).

78. *Id.*

79. *Cf. Crane v. Mathews*, 417 F. Supp. 532, 546 (N.D. Ga. 1976):

Certainly the imposition of co-payments, which financially burden recipients defined as the categorically needy in the Georgia Medicaid Program, may inhibit such individuals from seeking necessary medical services. The Georgia co-payment project has the effect of diminishing the amount of money that a family might have available for basic living needs and forces the family to make a determination whether to apply that money to basic living needs or to apply it to purchase medical care. Such an activity . . . [is one] which "deliberately and personally imposes" upon these human beings.

retary contended that

the regulations for the protection of human subjects are not intended to protect individuals from the "ordinary risks of daily life." There are certain risks which may reasonably be encountered by anyone, for example, the risks inherent in having to make a decision as to how to allocate funds, or in deciding whether to meet certain conditions, such as performing work, which are required in order to obtain funds. The exposure to the risks which emanate from these choices does not constitute the type of situation against which the Department's regulations are designed to guard.⁸⁰

The Secretary's interpretation of the definition of "subject at risk," probably an interpretative rule,⁸¹ is entitled to considerable weight,⁸² particularly by members of IRBs, researchers, and those who may practice before such boards. Board members can in good faith⁸³ rely on the interpretation in determining how to apply the definition.

IRBs are not bound by expansive interpretations of risk by other boards such as that in Georgia,⁸⁴ and that is particularly true

The court's language in dealing with the issue of whether the project implicated "human subjects" seems to comment almost poignantly, albeit indirectly, on the circumstances of those subjects as related to the issue of risk reserved by law to the IRB. The degree to which this influenced the subsequent deliberations cannot be known.

80. 41 Fed. Reg. 26,573 (1976).

81. 5 U.S.C. § 553(b)(A) (1970). See 1 K. Davis, *Administrative Law Treatise* § 5.03 (1958).

82. See 1 K. Davis, *supra* note 81, § 5.05.

83. On the importance of "good faith" as a necessary predicate for avoiding possible liability as an IRB member, see note 97 *infra*.

84. The Georgia State IRB's expansive view of "risk" following *Crane* illustrates an important problem with Commission Draft, *supra* note 8, at 9-10, as follows:

Recommendation (2)(A) Federal law should be enacted or amended to authorize the Secretary [of DHEW] to carry out the following duties:

(iii) Educational Activities to assist members of institutional review boards in recognizing and considering the ethical issues that are presented by research involving human subjects.

In its comment on this recommendation, the Commission explains that "DHEW should develop . . . mechanisms for reporting key IRB decisions to promote uniform treatment of similar protocols. Caution should be exercised, however, to avoid usurping the IRB's decision-making authority." *Id.* at 11.

It would be regrettable if the Georgia decision following *Crane* were to achieve the status of a "key decision." But compare the following:

In general ethical peer review is hampered by the fact that each committee operates in isolation and must consider every new issue on its own and without benefit of precedent. A case-reporting system, such as operates in the law, would make that unnecessary and would promote both equity among institutions and high standards.

Barber, *The Ethics of Experimentation with Human Subjects*, 234 *Scientific Am.*, Feb. 1976, at 25, 29-30 (1976).

where those interpretations are in conflict with interpretations promulgated by the Secretary of DHEW, the agency that is responsible for the regulations. Boards are free to interpret "risk" more narrowly, so long as they do not evade the minimal protective purpose of the DHEW regulations already discussed.

Whether boards adopt a narrow or restrictive definition of "subject at risk," such as the Secretary of DHEW urged in his interpretation, or a broader definition, such as that applied by the Georgia State IRB, can have a substantial impact on public health research. In terms of permissible methodologies of experimental research, the definition of risk can operate constrictively since, under the regulations, a determination that a subject is placed "at risk" triggers procedural safeguards which do not apply to other research. Put another way, under the regulations research in which subjects are not placed "at risk" is under no greater constraint than is research not involving human subjects at all (except that it must be passed on initially by the IRB).⁸⁵ It should be noted, of course, that professional ethics may impose constraints on research on human subjects that would not apply to research with mice or dice, but ethical considerations are not a part of the DHEW regulations and are not considered further here.⁸⁶

Subject "risk," as has been noted, is defined as "the possibility of injury, including physical, psychological, or social injury."⁸⁷ Con-

85. 45 C.F.R. § 46.102(b) (1976). *See also* Crane v. Mathews, 417 F. Supp. 532, 544-46 (N.D. Ga. 1976); 45 C.F.R. § 46.111(a) (1976).

86. *Cf.* Hershey & Miller, *supra* note 3, at 29: "Even though there might be no legal requirement to obtain consent when there are no risks, *investigators should seriously consider obtaining consent out of respect for human dignity*" (emphasis added).

On the ethical considerations of human experimentation, *see, e.g.*, Barber, *The Ethics of Experimentation with Human Subjects*, Scientific Am., Feb. 1976, at 25; Beecher, *Ethics and Clinical Research*, 274 New Eng. J. Med. 1354 (1966), *reprinted in* Biomedical Ethics, *supra* note 3, at 193; Dyck & Richardson, *The Moral Justification for Research Using Human Subjects, Use of Human Subjects in Safety Evaluation of Food Chemicals—Proceedings of a Conference* 229 Nat'l Acad. Sci. & Nat'l Research Council Pub. No. 1491 (1967), *reprinted in* Biomedical Ethics, *supra* note 3, at 243; Fletcher, *Human Experimentation: Ethics in the Consent Situation*, 32 L. & Contemp. Prob. 620 (1967); Fletcher, *Realities of Patient Consent to Medical Research*, 1 Hastings Center Studies 39 (1973), *reprinted in* Biomedical Ethics, *supra* note 3, at 261; Jonas, *Philosophical Reflections on Experimenting with Human Subjects*, 98 Daedalus 219 (1969), *revised in* H. Jonas, *Philosophical Essays: From Ancient Creed to Technological Man* (1974), *reprinted in* Biomedical Ethics, *supra* note 3, at 217; Shimkin, *Scientific Investigations on Man: A Medical Research Worker's Viewpoint, Use of Human Subjects in Safety Evaluation of Food Chemicals—Proceedings of a Conference* 217 Nat'l Acad. Sci. & Nat'l Research Council Pub. No. 1491 (1967), *reprinted in* Biomedical Ethics, *supra* note 3, at 207. "It is to be understood that no [statement of ethical] principles [that will assist the institution in discharging its responsibilities for protecting the rights and welfare of subjects] supersede[s] DHEW policy or applicable law." Institutional Guide, *supra* note 1, at 5.

87. 45 C.F.R. § 46.103(b) (1976).

sistent with the intent of the National Research Act of 1974, the regulations on institutional review leave considerable discretion⁸⁸ to the IRB members to define when risk exists for the human subjects of specific research projects. The use of the term "including" in connection with the catalog of potential areas of harm suggests that the scope of harm is not limited to those set out in the regulations.

Physical risk is perhaps the easiest example to understand, in large measure because medical and other researchers and even clinicians are familiar with physical consequences, iatrogenic (arising from therapeutic misadventures) and otherwise, which can and do occur, as well as their potential liability for intentionally and negligently caused physical harm. Risk of psychological harm is more difficult because of its emergent nature and nascent legal contours.⁸⁹ Although the concept of risk is not limited to what is defined in law to be a physical, psychological, or social risk, such an independent reference point in law may serve to guide an IRB in its determinations. Risks of harm which are not redressable at law may also be *de minimis* for research purposes as well and should be disregarded by IRBs along with conjectural and hypothetical views of harm.

Social harm includes such things as the risk of embarrassment, humiliation, stigma, and social or economic reprisal. It implicates, but probably differs from, the right to privacy.⁹⁰ Legal harm is an important adjunct to social risk and probably a distinct category of subject risk. Legal risks to subjects can arise from research into the use and effects of narcotics or alcohol when information supplied by the subject could serve as the basis for his criminal prosecution or for a civil action against him. Legal harm as a risk is suggested but not explored in the DHEW *Institutional Guide* to the regulations on human subjects' protection.⁹¹ Congress has specifically provided for

88. For a discussion of various aspects of IRB discretion, see pp. 449-50 *infra* and authorities cited notes 101-105 *infra*.

89. *Leong v. Takasaki*, 55 Haw. 398, 520 P.2d 758 (1974) (recovery for any resulting physical injury or objective manifestations of emotional distress). See also *Billings v. Atkinson*, 489 S.W.2d 858 (Tex. 1973); Comment, *Negligently Inflicted Mental Distress: The Case for an Independent Tort*, 59 Geo. L.J. 1237 (1971).

90. See W. Prosser, *supra* note 37, § 117.

91. There are . . . medical and biomedical projects concerned solely with organs, tissues, body fluids, and other materials obtained in the course of the routine performance of medical services such as diagnosis, treatment and care, or at autopsy. The use of these materials obviously involves no element of physical risk to the subject. However, their use for many research, training, and service purposes may present psychological, sociological, or legal risks to the subject or his authorized representatives.

Institutional Guide, *supra* note 1, at 3. Cf. *Hershey & Miller*, *supra* note 3, at 26, 52. See also Commission Draft, *supra* note 8, at 25, which states as follows:

eliminating subject risk with respect to drug and alcohol studies.⁹² Of course, the failure of an investigator to avail himself of this provision or the approval of such a project by an IRB without requiring the investigator to secure authorization to protect the subjects' privacy pursuant to the statute would expose the subject to risk, thus evidencing negligence on the part of the investigator and possibly a lack of good faith by members of the IRB.

Despite the provision for special protection of information and subject identities obtained in connection with drug and alcohol studies, other areas of research have no such safeguards. For instance, substantial probability of legal risk to subjects follows venereal disease research, which could give rise to information useful in a civil action for tortious infection,⁹³ or research into the battered child syndrome,⁹⁴ which could result in both civil⁹⁵ or criminal⁹⁶ liability.

In some studies, subjects would be placed at risk by the creation of documents linking them with an illegal or stigmatizing characteristic or behavior under study. The most secure method of protecting confidentiality of subjects in such studies is to create no written record of their identity, since such records are generally vulnerable to subpoena. Confidentiality assurances are available from the Department of Justice and the Department of Health, Education, and Welfare that may effectively protect such documents from subpoena in certain studies of illegal behavior or drug abuse. When such protection is not available in studies in which a breach of confidentiality may be harmful to subjects, and subjects might prefer that there be no documentation linking them with the research, the IRB may waive the requirement for documentation of consent in the interest of protecting the subject.

92. The Secretary [of DHEW] may authorize persons engaged in research on mental health, including research on the use and effect of alcohol and other psychoactive drugs, to protect the privacy of individuals who are the subject of such research by withholding from all persons not connected with the conduct of such research the names or other identifying characteristics of such individuals. Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding to identify such individuals.

42 U.S.C. § 242a(a) (1970 & Supp. IV 1974). The statute was upheld in *People v. Still*, 80 Misc. 2d 831, 364 N.Y.S.2d 125 (1975) (quashed subpoena duces tecum issued to employees of the methadone maintenance clinic), *modified*, 48 App. Div. 2d 366, 369 N.Y.S.2d 759 (1975); *People v. Newman*, 32 N.Y.2d 379, 298 N.E.2d 651, 345 N.Y.S.2d 502 (1973) (disclosure of pictures of patients taken in connection with a methadone program barred).

93. *E.g.*, *Crowell v. Crowell*, 180 N.C. 516, 105 S.E. 206 (1920), *rehearing denied*, 181 N.C. 66, 106 S.E. 149 (1921). See W. Prosser, *supra* note 37, § 18 at 105 & n.73.

94. See *The Battered Child* (2d ed. R. Helfer & C. Kempe eds. 1974). See also Hogue, *Book Review*, 65 Am. J. Pub. Health 414 (1975).

95. See W. Prosser, *supra* note 37, § 122 at 864-69.

96. Ark. Stat. Ann. § 42-807 (Repl. 1977). An example of a statute providing immunity to those reporting child abuse in good faith is Ark. Stat. Ann. § 42-814 (Repl. 1977). The following observations of Berger & Stallones, *supra* note 70, at 181, appear somewhat wide of the mark:

A final example of areas where confidentiality of research data conflicts with police powers concerns studies of causes and possible prevention of child abuse. Substan-

3. *Institutional Review Boards and Administrative Law*

Two problems with IRBs are readily apparent, only one of which can be addressed at the local level without revision of the DHEW Guidelines. The first problem concerns the excess discretion vested in IRBs and the need for a clear and coherent definition of subject "risk." A second and more fundamental problem is the allocation by DHEW of primary responsibility for protecting human subjects to the IRB rather than to a human subjects' advocate or ombudsman.

IRBs are creatures both of the federal regulations that require them of research institutions and of the institutions themselves. IRBs are bound to apply in good faith⁹⁷ the federal rules promulgated by DHEW. They may also, consistent with state law and institutional limitations, if any, promulgate their own rules—procedural and substantive.⁹⁸ Without attempting to set forth a complete model of such rules, it is sufficient to suggest here the need for a substantive definition of "risk" so that investigators will know what protocols and activities will result in a higher level of scrutiny and will trigger protective safeguards. An absence of a definition can lead to overzealous application of human subjects' protection by IRBs to the detriment of research to which the protection has little application.

tially standardized reporting laws in most states guarantee immunity from civil or criminal liability to anyone *who reports* suspected child abuse; indeed, legal pressure is oriented toward ensuring that suspected cases *are reported* to the appropriate state agency (usually the Welfare Department). Such legal provisions are strengthened by stipulations that fines, imprisonment or both may be levied against those who knowingly fail to report even suspected cases of child abuse or neglect. Implementation of this requirement is facilitated by provision for anonymous reporting.

(Emphasis added.)

The liability of subjects of research (*e.g.*, abusing parents or guardians), not investigators, is what the regulations for the protection of human subjects are concerned with. There is thus a real danger that, for example, research into accidents, accidents involving children (or their parents), or, more narrowly yet, child abuse, could expose subjects of such research to prosecution.

97. "Good faith" is necessary to avoid the imposition of liability and is a necessary predicate to indemnification in Arkansas. Ark. Stat. Ann. § 12-3401 (Repl. 1968 & Cum. Supp. 1977) provides indemnification for

damages adjudged . . . or . . . a compromise settlement . . . against officers or employees of the State of Arkansas . . . based on an act or omission by the officer or employee while acting without malice and in good faith within the course and scope of his employment and in the performance of his official duties.

See also *Wood v. Strickland*, 420 U.S. 308, rehearing denied, 421 U.S. 921 (1975); *Hogue, Board Member and Administrator Liability Since Wood v. Strickland*, 7 (U.N.C.) Sch. L. Bull. 1 (Oct. 1976).

98. See 45 C.F.R. § 46.106 (1976).

Hershey and Miller, in their work on the function of the IRB in a predominantly medical setting, depict the review process as informal, with the investigator and the IRB members apparently collaborating in the design of an inoffensive protocol. They state that "[i]nstitutional review should be an interactional process between the [IRB] and the investigator, striving to find a way that the proposed study can be performed in a manner consistent with public policy and the rights and welfare of the subjects, without destroying the worth of the study."⁹⁹

Ordinarily, interactional processes are unobjectionable, even salutary, in the academy, but interaction with an IRB guided by loosely defined and largely subjective concepts of risks to subjects is likely to lead to a one-sided contest with a detrimental effect to innovative research. Under federal regulations, investigators are dependent upon IRB approval for funding and for authority to conduct even unfunded studies. Review is pervasive. Investigators must expect repeated encounters with IRBs if their research routinely involves human subjects, and it is not likely that they will risk arguing over details at the expense of an ongoing relationship which every investigator must hope will be marked by good will.

Proposed recommendations have suggested continuity and stability in IRBs. These measures would foster competence and familiarity in dealing with problems but will likewise place active investigators further at the mercy of IRBs.¹⁰⁰ Since negative decisions by an IRB are not appealable,¹⁰¹ there are substantial opportunities for abuse of discretion by a board.

99. Hershey & Miller, *supra* note 3, at 14, 71-74.

100. IRB members should be appointed for a fixed term of at least a year and should not be removed during this term except for good cause. An IRB's membership should be relatively stable from year to year in order to enhance the experience of the IRB and to introduce stability into standards applied by the IRB.

Commission Draft, *supra* note 8, at 14.

101. "Board approvals, favorable actions and recommendations are subject to review and to disapproval or further restriction by the institutional officials. Board disapprovals, restrictions, or conditions cannot be rescinded or removed except by action of a Board described in the assurance approved by DHEW." 45 C.F.R. § 46.118 (1976).

In its proposed comment to *Recommendation (5)*, the National Commission has addressed this review problem as follows:

The Commission has not recommended a mechanism for appeal from IRB determinations, since it believes that an IRB should have the final word at its institution regarding the ethical acceptability of proposed research involving human subjects Should an institution wish to establish an appeals process, the Commission suggests that it be restricted to investigation of prejudice or unfairness and that the appeals board not be given authority to conduct a secondary review of the protocol or to reverse the IRB decision.

Commission Draft, *supra* note 8, at 32.

Concerning such abuses, Professor Kenneth Davis, who has written extensively about the problem of delegation,¹⁰² has proposed the following reformulation of the nondelegation doctrine to protect "against unnecessary and uncontrolled discretionary power":

The focus should no longer be exclusively on standards; it should be on the totality of protections against arbitrariness, including both safeguards and standards. The key should no longer be statutory words; it should be the protections the administrators in fact provide, irrespective of what statutes say or fail to say.¹⁰³

An effective prophylactic against abuse of IRB procedure would be a proper allocation of functions according to traditional administrative law models. For example, an IRB should consider limiting the scope of its inquiry into risk by a definition of "risk" as it is recognized in the department, school, or institution of which the IRB is a part. Such a definition should be arrived at after soliciting information and proposals from affected parties.¹⁰⁴ Such a definition would circumscribe the work of the IRB and prevent the abuse of its discretion in the interaction between investigators and the board.¹⁰⁵

As a second step, the review process should be tailored along the lines of an adjudicatory hearing with minimal due process re-

102. E.g., K. Davis, *Discretionary Justice—A Preliminary Inquiry* (1969).

103. Davis, *A New Approach to Delegation*, 36 U. Chi. L. Rev. 713 (1969). See also *Environmental Defense Fund, Inc. v. Ruckelshaus*, 439 F.2d 584, 598 (D.C. Cir. 1971) (Bazelon, C.J.):

Judicial review must operate to ensure that the administrative process itself will confine and control the exercise of discretion. Courts should require administrative officers to articulate the standards and principles that govern their discretionary decisions in as much detail as possible. Rules and regulations should be freely formulated by administrators, and revised when necessary. Discretionary decisions should more often be supported with findings of fact and reasoned opinions.

(Citing K. Davis, *Discretionary Justice—A Preliminary Inquiry* (1969)) (footnotes omitted). Cf. Sax, *The (Unhappy) Truth About NEPA*, 26 Okla. L. Rev. 239 (1973) ("I know of no solid evidence to support the belief that requiring articulation, detailed findings or reasoned opinions enhances the integrity or propriety of the administrative decisions. I think the emphasis on the redemptive quality of procedural reform is about nine parts myth and one part coconut oil").

104. For discussion of rule-making hearings based on legislative facts, see 1 K. Davis, *Administrative Law Treatise*, § 7.04 (1958); Davis, *An Approach to Problems of Evidence in the Administrative Process*, 55 Harv. L. Rev. 364, 402-16 (1942); Friendly, "Some Kind of Hearing" 123 U. Pa. L. Rev. 1267 (1975).

105. E.g., *Yick Wo v. Hopkins*, 118 U.S. 356, 366 (1886) ("The power given . . . is not confided to their discretion in the legal sense of that term, but is granted to their mere will. It is purely arbitrary and acknowledges neither guidance nor restraint"). For a discussion of the constitutional dimension of this problem, see Hogue, *Eastlake and Arlington Heights: New Hurdles in Regulating Urban Land Use?* 28 Case Ws. Res. L. Rev. 41, 70 n.174 (1977).

quired.¹⁰⁶ Since the investigator will have had an opportunity in most instances to explain his protocol, it is worth emphasizing that due process would require notice of an adverse decision, its basis, and an opportunity to respond orally and/or in writing to the reasons given. Oral argument is particularly desirable in view of the absence of any appeals process. It is interesting to note that a recommendation for more protection than is currently required by due process was incorporated in the proposals of the National Commission.¹⁰⁷

In some instances it may be desirable to achieve greater procedural protection for investigators by bringing the IRBs at state-owned institutions under the state's administrative procedure act.¹⁰⁸ The Model State Administrative Procedure Act¹⁰⁹ provides a useful

106. *Londoner v. Denver*, 210 U.S. 373 (1908). *Cf. Bi-Metallic Inv. Co. v. State Bd. of Equalization*, 239 U.S. 441 (1915).

107. Commission Draft, *supra* note 8, at 28 states as follows: "Recommendation (5) . . . The Secretary should require, further, that an institutional review board inform investigators of the basis of decisions to disapprove or require the modification of proposed research and give investigators an opportunity to respond in person or in writing."

108. *E.g.*, Ark. Stat. Ann. §§ 5-701 to -715 (Repl. 1976); N.C. Gen. Stat. § 150A-1 (Repl. 1974 & Cum. Supp. 1977).

Independent bodies such as IRBs are apparently not subject to the federal Administrative Procedure Act (APA), 5 U.S.C. §§ 500-706 (1970). *See Washington Research Project, Inc. v. Department of HEW*, 366 F. Supp. 929 (D.D.C. 1973), *modified*, 504 F.2d 238 (D.C. Cir. 1974), *cert. denied*, 421 U.S. 963 (1975) (initial review groups (IRGs) of outside consultants required for project approval not subject to APA's freedom of information provisions).

Some states expressly exclude educational institutions and their constituent bodies from state administrative procedure acts. For example, the North Carolina exclusion is as follows:

Article 4 of this Chapter, governing judicial review of final agency decisions, shall apply to the University of North Carolina and its constituent or affiliated boards, agencies, and institutions, but the University of North Carolina and its constituent or affiliated boards, agencies, and institutions are specifically exempted from the remaining provisions of this Chapter.

N.C. Gen. Stat. § 150A-1(a) (Cum. Supp. 1977).

See generally Daye, *North Carolina's New Administrative Procedure Act: An Interpretive Analysis*, 53 N.C.L. Rev. 833, 842 n.44 (1975).

Final negative determinations by an IRB under 45 C.F.R. § 46.118 (1976) at a branch of the state university would appear to be reviewable in superior court under N.C. Gen. Stat. § 150A-43 to -52 (Repl. 1974 & Cum. Supp. 1977). The scope of review is limited, but where the record of the proceeding is inadequate and at the discretion of the trial judge, review may be *de novo*. N.C. Gen. Stat. §§ 150A-50 to -51 (Repl. 1974 & Cum. Supp. 1977).

109. 13 U.L.A. 347 (Supp. 1978), enacted with variations as follows: Ark. Stat. Ann. §§ 5-701 to -715 (Repl. 1976); Conn. Gen. Stat. Ann. §§ 4-166 to -189 (West Supp. 1978); D.C. Code §§ 1-1501 to -1510 (Supp. II 1975); Ga. Code Ann. §§ 3A-101 to -124 (Rev. 1975); Haw. Rev. Stat. §§ 91-1 to -18 (Repl. 1976); Idaho Code §§ 67-5201 to -5218 (1973 & Cum. Supp. 1977); Ill. Ann. Stat. ch. 127, §§ 1001-1021 (Smith-Hurd Cum. Supp. 1978); Iowa Code Ann. §§ 17A.1-.23 (West 1978); La. Rev. Stat. Ann. §§ 49:951-.967 (West Cum. Supp. 1978); Md. Code Ann. §§ 41-244 to -256A (Repl. 1971); Mich. Comp. Laws Ann. §§ 24.201-.315 (Cum. Supp. 1978); Mo. Ann. Stat. §§ 536.010-.150 (Vernon 1953 & Cum. Supp. 1978); Mont. Rev. Codes Ann. §§ 82-4201 to -4225 (Cum. Supp. 1977); Neb. Rev. Stat. §§ 84-901 to -919 (Supp. 1973); Nev. Rev. Stat. §§ 233B.010-.160 (1975); N.H. Rev. Stat. Ann. §§ 541-A:1 to -A:9 (Repl. 1974); N.Y. State Admin. Proc. Act (McKinney Special Pamphlet 1977); N.C. Gen.

example amply solicitous of investigators' interests. Any inclusion of IRBs within a state administrative procedure act would, however, have to be approved by the Secretary of DHEW¹¹⁰ as a part of an institution's general assurances of compliance.

It is important to note that merely because an IRB responds to the supposed interests of human subjects does not mean either that such subjects are properly represented or even that their interests are adequately articulated. Nor does the presence of a nonprofessional on the IRB, a "consumer" or community member, alleviate

Stat. §§ 150A-1 to -64 (Repl. 1974 & Cum. Supp. 1977); Okla. Stat. Ann. tit. 75, §§ 301-327 (West 1976 & Cum. Supp. 1978); R.I. Gen. Laws §§ 42-35-1 to -35-18 (Reen. 1977); S.D. Compiled Laws Ann. §§ 1-26-1 to -26-40 (Rev. 1974); Tenn. Code Ann. §§ 4-502 to -527 (Repl. 1971 & Cum. Supp. 1977); Vt. Stat. Ann. tit. 3, §§ 801-820 (1975 Cum. Supp.); Wash. Rev. Code Ann. §§ 34.04.010-.940 (1965 & Supp. 1976); W. Va. Code §§ 29A-1-1 to -7-4 (Repl. 1976 & Cum. Supp. 1977); Wis. Stat. Ann. §§ 227.01-.26 (West 1957); Wyo. Stat. §§ 9-276.19 to -276.33 (Cum. Supp. 1975).

110. See 45 C.F.R. § 46.106 (1976). The Commission Draft, *supra* note 8, at 32, recognizes the possibility of IRBs being subject to state as well as federal law. Thus, the Commission "supports the principle of open meetings. The public generally should have access to IRB meetings, limited only by local law or a decision by the IRB to close a meeting in order to discuss personal or proprietary information." The impact of state open meetings or sunshine laws should probably be noted in the general assurance to DHEW. Laws will, of course, differ in their applicability to IRBs; some will be required to comply while others will not. *But see* Student Bar Ass'n Bd. of Governors v. Byrd, 293 N.C. 594, 239 S.E.2d 415 (1977) (North Carolina's open meetings statute, N.C. Gen. Stat. § 143-318.1 to -318.6 (Repl. 1974 & Cum. Supp. 1977) held inapplicable to meetings of the faculty of the law school; the law faculty held not a part of a governmental body acting as body politic). *Accord*, Fain v. Faculty of the College of Law, 552 S.W.2d 752 (Tenn. 1977); McLarty v. Board of Regents, 231 Ga. 22, 200 S.E.2d 117 (1973) (faculty-student committee to recommend allocation of revenues from student fees), *cited with approval* in Arkansas Gazette Co. v. Pickens, 258 Ark. 69, 79, 522 S.W.2d 350, 356 (1975) (Fogleman, J., concurring). *Contra*, Cathcart v. Andersen, 85 Wash. 2d 102, 530 P.2d 313 (1975) (law faculty).

Open meetings in Arkansas are governed by the Freedom of Information Act (FOIA) Ark. Stat. Ann. § 12-2805 (Repl. 1968), which requires public meetings of "all boards, bureaus, commissions, or organizations" of the state "supported wholly or in part by public funds, or expending public funds" to be open. Exceptions are limited to sessions "considering employment, appointment, promotion, demotion, disciplining or resignation of any public officer or employee." The sanction for noncompliance is to void any public business not within the exception that is conducted in executive session and not reenacted in a public session. *Id.* § 12-2805(b). Injunctions are available to excluded parties. *Id.* § 12-2806. Arkansas' FOIA incorporates two standards. Its application to units of local government is limited by § 12-2805 to "governing bodies" and is possibly subject to the narrow construction followed in other states in the *Student Bar Ass'n* and *Fain* cases discussed above. The broad scope of § 12-2805, however, would preclude a narrower application of the statute when units of state government are involved. *Arkansas Gazette Co. v. Pickens*, 258 Ark. 69, 522 S.W.2d 350 (1975) (committees of the university's board of trustees). The Commission proposal that "IRBs should make provision to consider requests by investigators to close meetings or portions of meetings at which their research proposals will be discussed," Commission Draft, *supra* note 8, at 32, is not within the authorized exceptions to Arkansas' FOIA. See also Nat'l Comm'n for the Protection of Human Subjects of Biomedical and Behavioral Research, Disclosure of Research Information under the Freedom of Information Act (1977).

the problem. The purpose of the community member is to enhance the collective expertise of the board and alleviate the possibility of professional bias in the ethical perspective of the board. So the addition needed in the IRB review process is an independent spokesman for the interests of potential human subjects, a human subjects' advocate or ombudsman¹¹¹ charged with identifying and articulating the interests of subjects and representing their position before the board. It is submitted that this proposal would require a change in the DHEW regulations since present regulations impose primary responsibility for subject protection on the IRB. Inherent in this proposal is a partial transfer of that responsibility from the IRB, which would become more neutral in its stance and better able to weigh independently the information presented to it by the investigator and the human subjects' rights advocate. At the same time, primary responsibility for advocating subjects' interests would rest with the ombudsman. Institutions could, however, experiment with this proposal without shifting responsibility, assuming they file a revised general assurance with DHEW and secure the Secretary's approval.

Many of the problems explored in this article, such as IRB abuses in expansively construing the concept of risk, can be traced directly to the structure of the IRB and its procedure as prescribed by DHEW regulations. Under present rules, the board is to function both as an advocate for the human subjects of the experiment and as an impartial decision-maker passing on a project's acceptability.

111. The term "ombudsman" is not intended in a limited, technical sense. See Verkuil, *The Ombudsman and the Limits of the Adversary System*, 75 Col. L. Rev. 845, 847 & n.10 (rejecting the narrower concept espoused in *The Ombudsman: Citizen's Defender*, xii (D. Rowat ed. 1968)). The human subjects' rights advocate is analogous to the public counsellor incorporated into the administrative procedure of some state and federal agencies. *E.g.*, 45 U.S.C. §§ 715(a),(d)(2) (Supp. 1976) (Rail Service Planning Office within the Interstate Commerce Commission); Cal. Pub. Res. Code §§ 25217(b), 25222 (West Cum. Supp. 1975) (advisor to California Energy Resources Conservation and Development Commission); 14 C.F.R. §§ 302.9, 384.7 (1975) (consumer advocate participating in deliberations of the Civil Aeronautics Board). See also Bloch & Stein, *The Public Counsel Concept in Practice: The Regional Rail Reorganization Act of 1973*, 16 Wm. & Mary L. Rev. 215 (1974); Comment, *The Office of Public Counsel: Institutionalizing Public Interest Representation in State Government*, 64 Geo. L.J. 895 (1976).

The literature on the ombudsman is extensive. *E.g.*, W. Gellhorn, *When Americans Complain: Governmental Grievance Procedures* (1966); Cramton, *A Federal Ombudsman*, 1972 Duke L.J. 1; Davis, *Ombudsman In America: Officers to Criticize Administrative Action*, 109 U. Pa. L. Rev. 1057 (1961); Frank, *The Nebraska Public Counsel—The Ombudsman*, 5 Cum.—Sam. L. Rev. 30 (1974); Comment, *A State Statute to Create the Office of Ombudsman*, 2 Harv. J. Legis. 213 (1965).

The role of ombudsman or public counsel is allocated by law in some instances to the state's attorney general. *E.g.*, Ark. Stat. Ann. §§ 70-901 to -929 (Cum. Supp. 1977) (Consumer Protection Division within the office of the Attorney General).

The fusion of these functions naturally leads to a blurring of responsibility that should be kept distinct. The IRB has the power to approve or disapprove a proposal; it is the expert decision-making body. The investigator presents his view of the proposal to the board, including his perspective on potential harm to subjects. What is lacking is an independent assessment by an individual charged with presenting the subjects' interests. The present regulations require both the investigator and the IRB to consider subjects' interests, but obviously an investigator's other responsibilities affect his ability to discharge that duty. In fact, the IRB requirement arose out of an obvious inability to entrust investigators with sole responsibility for subjects. It is not surprising that IRBs saddled with a dual task—protecting subjects and approving (or disapproving) projects—tend to give considerable attention to interests of the unrepresented. Lawyers who have witnessed a court's solicitude for a pro se litigant matched against qualified legal counsel will recognize the problem.

Conclusion

The requirement of ethical peer review in the form of IRBs to protect human subjects of biomedical and behavioral research was a much-needed response to some obvious abuses, particularly in medical research. The protection provided by IRBs should be for real and substantial harms defined in advance by a process of rule-making reflective of scientific consensus in a given department, school, or institution. This is particularly appropriate for public health and other types of nontherapeutic research. At the same time, some consideration should be given to protecting investigators from an abuse of discretion by IRBs by adopting standards and incorporating practices based on minimal notions of due process.