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The Law and Ethics of Psychosocial Research on AIDS

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The Law and Ethics of Psychosocial Research on AIDS

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I. GENERAL ISSUES IN THE LAW AND ETHICS OF PSYCHOSOCIAL RESEARCH

A. The Nature of the Issues

Few topics of legal and ethical inquiry raise so starkly the proper ordering of the interests of society and the individual as does research with human participants.¹ Such research is important to understanding the human condition and advancing human welfare,² but it requires *using* people—making them the *subjects*³ of the researcher's investigation. Participants rarely stand to gain direct significant benefit from their investment of time and energy.⁴ At most, they typically acquire whatever good feeling comes from altruism,⁵ perhaps some in-

1. See generally G. ANNAS, L. GLANTZ & B. KATZ, INFORMED CONSENT TO HUMAN EXPERIMENTATION (1977); B. BARBER, J. LALLY, J. MAKARUSKA & R. D. SULLIVAN, RESEARCH ON HUMAN SUBJECTS (1973); THE ETHICS OF SOCIAL RESEARCH (J. Sieber ed. 1982) [hereinafter cited as SOCIAL RESEARCH]; B. GRAY, HUMAN SUBJECTS IN MEDICAL EXPERIMENTATION (1975); J. KATZ, EXPERIMENTATION WITH HUMAN BEINGS: THE AUTHORITY OF THE INVESTIGATOR, SUBJECT, PROFESSIONS, AND STATE IN THE HUMAN EXPERIMENTATION PROCESS (1972); NAT'L COMM'N FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL & BEHAVIORAL RESEARCH, THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH (1979) [hereinafter cited as BELMONT REPORT].
2. Advances in empirical knowledge of most important aspects of human behavior and experience require research with human participants: e.g., health; mental health; crime; consumer behavior; organizational functioning; education; human factors in productivity, use of machines, and function of architectural design; family relationships; race relations; and conflict and conflict resolution.
3. Although use of the term *subject* is common in human research, see, e.g., Protection of Human Subjects, 45 C.F.R. pt. 46 (1984), we will rely upon the term *participant*, to connote the partnership between researcher and participant, and the latter's autonomy in deciding whether to become involved in a study. Cf. J. KATZ, THE SILENT WORLD OF DOCTOR AND PATIENT (1984) (exploring the dynamics and ethics of the status of physician and patient in decisions about treatment).
4. Whether participants will obtain direct benefit from a study changes the calculus in the level of risk permissible in research involving participants who may be unable to give fully competent, voluntary consent. See, e.g., Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects, 45 C.F.R. §§ 46.301 to 46.306 (1984) [hereinafter cited as Protections for Prisoners]; Additional Protections for Children Involved as Subjects in Research, 45 C.F.R. §§ 46.401 to 46.409 (1984).
5. The potential moral benefit to participants from doing good for society has been a focus of the debate on whether children should be permitted to participate in

tellectual stimulation,⁶ and possibly token sums of money or other compensation.⁷ In short, research with human participants is typically for the social good, not the welfare of the individual.

Complicating the situation is the fact that researchers' interests may not be coextensive with those of society. Academic inquiry is generally assumed to be in the public interest, especially when the topic of investigation is consensually acknowledged to be a matter of great public concern.⁸ However, even in cases in which the topic is a matter of great moment—perhaps *especially* in such circumstances—researchers have substantial property interests in their work.⁹ Tenure, promotion, merit pay, and the esteem of peers and the educated public all may be contingent upon conduct of research of ample quantity and significance. For scholars in disciplines in which human behavior, anatomy, or physiology is the topic of inquiry,¹⁰ investment by human participants in their research is crucial to economic and social status. Whatever the benefits to the public and the risks to participants in such research, scholars have a vested interest in stimulating participation in research and guarding the conditions under which research is conducted and the findings are disseminated.¹¹

research even when they are incompetent to consent to it. *See, e.g.,* McCormick, *Experimentation in Children: Sharing in Sociality*, HASTINGS CENTER REP., Dec. 1976, at 41; Ramsay, *Children as Research Subjects: A Reply*, HASTINGS CENTER REP., Apr. 1977, at 40; Ramsay, *The Enforcement of Morals: Nontherapeutic Research on Children*, HASTINGS CENTER REP., Aug. 1976, at 21.

6. The use of undergraduates in research to fulfill course requirements is justified by the knowledge about the research endeavor that is expected to accrue to participants. COMM. FOR THE PROTECTION OF HUMAN PARTICIPANTS IN RESEARCH OF THE AM. PSYCHOLOGICAL ASS'N, ETHICAL PRINCIPLES IN THE CONDUCT OF RESEARCH WITH HUMAN PARTICIPANTS 32-33 (1982) [hereinafter cited as APA, COMMENTARY ON ETHICAL PRINCIPLES].
7. There is a paradox of purpose in compensation of participants in research from which they would not otherwise obtain benefit. On the one hand, some compensation is ethically desirable and perhaps pragmatically necessary in order to obtain volunteers for research that is especially time-consuming, tedious, or risky. On the other hand, the principle of distributive justice requires that risks associated with research should not be borne exclusively by those particularly in need of money or other benefits. The irony is that adequate compensation may be perceived as diminishing voluntariness of consent. *See, e.g.,* Protections for Prisoners, *supra* note 4, at §§ 46.305(2), (6).
8. *See, e.g.,* Dow Chem. Co. v. Allen, 672 F.2d 1262, 1275 (7th Cir. 1982); Andrews v. Eli Lilly & Co., 97 F.R.D. 494, 500-03 (N.D. Ill. 1983); Richards of Rockford, Inc. v. Pacific Gas & Elec. Co., 71 F.R.D. 388, 400 (N.D. Cal. 1976).
9. *See, e.g.,* Dow Chem. Co. v. Allen, 672 F.2d 1262, 1276 (7th Cir. 1982); Andrews v. Eli Lilly Co., 97 F.R.D. 494, 500-03 (N.D. Ill. 1983).
10. Disciplines in which research often requires human participants are wide-ranging: *e.g.,* psychology, sociology, anthropology, marketing, economics, education, political science, biology, medicine and the other health sciences, and home economics.
11. *See generally* D. NELKIN, SCIENCE AS INTELLECTUAL PROPERTY: WHO CONTROLS SCIENTIFIC RESEARCH? (1984). The protection of trade secrets in business is

Although there may be few "mad scientists" flagrantly exploiting and harming participants for a bit of knowledge (and the prestige and pecuniary benefits that accrue from it), there have been a number of controversial experiments in recent decades that have stimulated regulation of human research, both by government and the scientific professions themselves. Doubtless, the most notorious examples were Nazi physicians' gruesome experiments on concentration camp prisoners.¹² These led to the promulgation of the Nuremberg Code,¹³ which remains the most comprehensive, and perhaps the most restrictive,¹⁴ statement of the law of informed consent to research. In addition, concern over several American medical studies in which participants were subjected to harmful stimuli¹⁵ led to additional professional guidelines¹⁶ and, ultimately, federal regulation.¹⁷

The potential risks to participants from biomedical research are easy to comprehend. When participants ingest an untried drug, they are obviously assuming an unknown risk to their health. If healthy, they may subject themselves to unnecessary physical harm, and, if ill, they risk exacerbating their preexisting medical condition, losing access to existing, more effective treatments, and acquiring new medical problems. Even relatively innocuous medical studies may involve some discomfort that would not otherwise be incurred, for example, having one's finger pricked for a blood sample.

analogous. See, e.g., *Andrews v. Eli Lilly Co.*, 97 F.R.D. 494, 501-02 n.24 (N.D. Ill. 1983).

12. See *United States v. Brandt*, reprinted in 1-2 TRIALS OF WAR CRIMINALS BEFORE THE NUREMBERG MILITARY TRIBUNALS (1948).
13. NUREMBERG CODE, reprinted in 143 SCI. 553 (1964).
14. The Nuremberg Code prohibits any research in which participants have not given fully informed consent. *Id.* at § 1. Therefore, it bars any research involving persons who, because of immaturity or mental disability, are incompetent to consent to research. It also bars any research using deception or incomplete disclosure.
15. See, e.g., *The Jewish Chronic Disease Hospital Case*, in J. KATZ, *supra* note 1, at 9; Benson & Smith, *The Harvard Drug Controversy: A Case Study of Subject Manipulation and Social Structure*, in ETHICS, POLITICS, AND SOCIAL RESEARCH (G. Sjöberg ed. 1967); Goldby, *Experiments at the Willowbrook State School*, 1 LANCET 749 (1971).
16. E.g., AM. ANTHROPOLOGICAL ASS'N, PRINCIPLES OF PROFESSIONAL RESPONSIBILITY (1971); AM. MED. ASS'N, ETHICAL GUIDELINES FOR CLINICAL INVESTIGATION (1966); AM. SOCIOLOGICAL ASS'N, CODE OF ETHICS (1971); DECLARATION OF HELSINKI, RECOMMENDATIONS GUIDING DOCTORS IN CLINICAL RESEARCH (1964); SOC'Y FOR RESEARCH IN CHILD DEV., ETHICAL STANDARDS FOR RESEARCH WITH CHILDREN (1973); Am. Psychological Ass'n, *Ethical Principles of Psychologists*, 36 AM. PSYCHOLOGIST 633 (1981) [hereinafter cited as APA Principles]. See also APA, COMMENTARY ON ETHICAL PRINCIPLES, *supra* note 6 (commentary on *Ethical Principles of Psychologists*). A detailed discussion of the manner in which these and other professional codes strive to protect privacy may be found in Winslade & Ross, *Privacy, Confidentiality and Autonomy in Psychotherapy*, 64 NEB. L. REV. 578 (1985).
17. Protection of Human Subjects, 45 C.F.R. pt. 46 (1984).

Although there have been a few dramatic examples of social science research of questionable ethics,¹⁸ most human research in the social sciences involves no obvious risk of harm. It is likely few people would be outraged by its continuation absent any regulation. For example, the greatest risk to participants in most studies in cognitive psychology is probably boredom,¹⁹ a consequence that is unlikely to stimulate a great social movement for reform.

Nonetheless, the basic dilemma of the proper use of individuals for the good of society and/or the researcher is present even in social science research.²⁰ At a minimum, the research usually requires investment of participants' time without clear benefit to the participants themselves. Moreover, although participants may not be *harmed* by psychosocial research, they still may be *wronged* through unethical or questionable ethical practices. Perhaps the most controversial and obvious example of such a practice is the use of deception in social psychological experiments.²¹ Even if there is no effect from being the target of lies by an investigator, the manipulation of the participant in such a way may violate moral imperatives.²² A more subtle issue is that much psychological and sociological research involves private as-

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18. *E.g.*, L. HUMPHREYS, TEAROOM TRADE: IMPERSONAL SEX IN PUBLIC PLACES (1970); S. MILGRAM, OBEDIENCE TO AUTHORITY: AN EXPERIMENTAL VIEW (1974); Middlemist, Knowles & Matter, *Personal Space Invasions in the Lavatory: Suggestive Evidence for Arousal*, 33 J. PERSONALITY & SOC. PSYCHOLOGY 541 (1976). *See also* Baumrind, *Some Thoughts on Ethics of Research: After Reading Milgram's Behavioral Study of Obedience*, 19 AM. PSYCHOLOGIST 421 (1964); Koocher, *Bathroom Behavior and Human Dignity*, 35 J. PERSONALITY & SOC. PSYCHOLOGY 120 (1977) (discussing Middlemist, Knowles & Matter, *supra*). *See generally* SOCIAL RESEARCH, *supra* note 1.
 19. APA, COMMENTARY ON ETHICAL PRINCIPLES, *supra* note 6, at 17. The participant's task might include tracking movement of a light, memorizing pairs of nonsense syllables, or pressing a button whenever a particular symbol appears on a screen. Such studies sometimes include hundreds of trials. Participants will sometimes sit for hours complying with an experimenter's request to engage in a meaningless task, such as adding columns of numbers repeatedly or tearing strips of papers. *See generally* Orne, *On the Social Psychology of Psychological Experiment: With Particular Reference to Demand Characteristics and their Implications*, 17 AM. PSYCHOLOGIST 776 (1962).
 20. *See* Cassell, *Harms, Benefits, Wrongs, and Rights in Fieldwork*, in SOCIAL RESEARCH: FIELDWORK, REGULATION, AND PUBLICATION, *supra* note 1, at 7. Sieber, *Ethical Dilemmas in Social Research*, in SOCIAL RESEARCH: SURVEYS AND EXPERIMENTS, *supra* note 1, at 1.
 21. *See, e.g.*, Adair, Dushenko, & Lindsay, *Ethical Regulations and their Impact on Research Practice*, 40 AM. PSYCHOLOGIST 59 (1985); Baumrind, *Research Using Intentional Deception: Ethical Issues Revisited*, 40 AM. PSYCHOLOGIST 165 (1985); Geller, *Alternatives to Deception: Why, What, and How?*, in SOCIAL RESEARCH: SURVEYS AND EXPERIMENTS, *supra* note 1, at 39; Kelman, *Human Use of Human Subjects: The Problem of Deception in Social Psychological Experiments*, 67 PSYCHOLOGICAL BULL. 1 (1967); Smith, *Some Perspectives on Ethical/Political Issues in Social Science Research*, 2 PERSONALITY & SOC. PSYCHOLOGY BULL. 445 (1976).
 22. *See generally* S. BOK, LYING: MORAL CHOICE IN PUBLIC AND PRIVATE LIFE (1978);

pects of individual and group behavior.²³ As such, there is some intrusiveness involved. Simply asking questions about personal matters or "unobtrusively" observing behavior²⁴ may inherently involve a cost in participants' privacy.

B. The Ethical and Legal Framework

Recognizing these ethical problems and the potential conflicts of interest among social scientists, the public, and participants, the relevant professional organizations and the federal government have enacted codes of ethics for the conduct of social science research involving human participants.²⁵ The most detailed code is that of the American Psychological Association (APA).²⁶ The overriding obligation imposed on psychologists by their ethical principles is to "respect the dignity and worth of the individual and strive for the preservation and protection of fundamental human rights."²⁷ Researchers must consider the welfare of participants²⁸ and guard their civil rights.²⁹ This basic emphasis on the integrity and worth of the individual is balanced by the responsibility to use professional skills to increase knowledge useful in the promotion of human welfare.³⁰ These general principles are set forth in ten principles, all with amplification in subprinciples, totaling six pages. There are references to research ethics throughout the ethical principles³¹ and, as psychologists, researchers are bound by the principles as a whole. The specific framework for

Freedman, *Man Bites Dog: A Bioethicist's Deception*, 5(5) IRB 8 (1983); Murray, *Was this Deception Necessary?*, 2(10) IRB 7 (1980).

23. See generally Ruebhausen & Brim, *Privacy and Behavioral Research*, 65 COLUM. L. REV. 1184 (1965).
24. Unobtrusive measurement refers to research in which participants are studied without their knowledge. See generally E. WEBB, D. CAMPBELL, R. SCHWARTZ & L. SECHREST, UNOBTUSIVE MEASURES: NONREACTIVE RESEARCH IN THE SOCIAL SCIENCES (1966).
25. Protection of Human Subjects, 45 C.F.R. pt. 46 (1984); AM. ANTHROPOLOGICAL ASS'N, *supra* note 16; AM. SOCIOLOGICAL ASS'N, *supra* note 16; SOC'Y FOR RESEARCH IN CHILD DEV., *supra* note 16; APA Principles, *supra* note 16.
26. APA Principles, *supra* note 16. See also COMMENTARY ON ETHICAL PRINCIPLES, *supra* note 6.
27. APA Principles, *supra* note 16, at 633 (Preamble).
28. *Id.* at 633, 636, 637-38 (Preamble, Principles 6 & 9).
29. *Id.* at 634 (Principle 3c).
30. *Id.* at 633, 637-38 (Preamble & Principle 9).
31. See, e.g., *id.* at 633 (Principle 1a) (reporting of research so as to minimize misleading and prejudicial uses of research); *id.* (Principle 1b) (clarification in advance of expectations for sharing of research); *id.* at 634 (Principle 3d) (conflicts between ethics and law); *id.* at 635 (Prin. 5c) (confidentiality of records); *id.* at 637 (Principle 7e) (obtaining approval for research in institutions or organizations); *id.* (Principle 7f) (distribution of publication credit); *id.* at 638 (Principle 10) (research with animals).

research with human participants is found in Principle 9.³² The principles relating to research are periodically revised and interpreted by the APA Committee for the Protection of Human Participants in Research and the APA Ethics Committee, the latter of which also adjudicates complaints relating to possible ethical violations.

The primary legal framework for the protection of human participants in social science research is found in the regulations of the Department of Health and Human Services.³³ The regulations are based on the work of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research³⁴ and its successor, the President's Commission.³⁵ In a document known as the Belmont Report,³⁶ the National Commission stated three basic ethical principles that should govern research with human participants. First, *respect for persons* entails "the requirement to acknowledge autonomy and the requirement to protect those with diminished autonomy."³⁷ Second, the principle of *beneficence* requires the avoidance of harm and the maximization of possible benefits.³⁸ Third, the principle of *justice* mandates fair distribution of the burdens of participation in research and of assumption of risks associated with research.³⁹

In view of the similar value placed on human dignity and welfare, it is not surprising that the procedures established as requirements of professional ethical practice by the Ethical Principles of Psychologists and as requirements of law by the federal regulations are very similar. Both require minimization of risk to participants⁴⁰ and weighing of risks and benefits to ensure that the study is worth doing.⁴¹ The investigator is obligated to seek ethical advice in determining that the potential benefits of the study substantially outweigh risks associated

32. Principle 9, *id.* at 637-38, consists of a preamble and 10 sub-principles. The principle is organized roughly around the chronology of the design, conduct, analysis, and reporting of a study.

33. Protection of Human Subjects, 45 C.F.R. pt. 46 (1984). All research funded by the Department of Health and Human Services (HHS) is covered by the regulations. 45 C.F.R. § 46.101(a) (1984). Institutions receiving funds from HHS also must make provisions for review of research involving human participants that is not federally funded, 45 C.F.R. § 46.103(a)(1) (1984). As a practical matter, this section of the regulations makes them applicable to all research conducted by universities, schools, and health care facilities.

34. The Commission was authorized by statute. See National Research Act, Pub. L. 93-348, 88 Stat. 342, 348 (1974).

35. Public Health Service Act, 42 U.S.C. § 300v (1982).

36. BELMONT REPORT, *supra* note 1.

37. *Id.* at 4.

38. *Id.* at 4-5.

39. *Id.* at 5.

40. 45 C.F.R. § 46.111(1) (1984); APA, *supra* note 16, at 637-38 (Principles 9, 9b, & 9g).

41. 45 C.F.R. § 46.111(2) (1984); APA, *supra* note 16, at 633, 637 (Principles 1a, 9, & 9a).

with the research procedures.⁴² As a general rule, researchers are required to seek informed consent from participants,⁴³ honor their freedom not to participate or to withdraw from participation,⁴⁴ and protect their privacy and the confidentiality of data.⁴⁵ The Ethical Principles of Psychologists go beyond the federal regulations to require not only that the design and conduct of research are in accordance with basic ethical principles, but that the results are reported in ethical fashion.⁴⁶ Psychologists are obligated to "minimize the possibility that their findings will be misleading . . . especially where their work touches on social policy or might be construed to the detriment of persons in specific age, sex, ethnic, socioeconomic, or other social groups."⁴⁷ At the same time, they are supposed not to suppress data.⁴⁸

II. THE NATURE AND EPIDEMIOLOGY OF AIDS

A. Factors Contributing to the Sensitivity of Research on AIDS

The conflicts of interest that sometimes arise in psychosocial research—and the ethical and legal problems that result—are illustrated most vividly by research on socially sensitive topics.⁴⁹ Generally, such topics involve matters of great public import. In order for policy about such matters to develop rationally, relevant knowledge is needed. In some sense, this need is most acute for the groups under study.⁵⁰ On

42. Under the federal regulations, 45 C.F.R. pt. 46 (1984), most research is subject to review by an institutional review board (IRB) composed of representatives of diverse disciplinary and social backgrounds. *Id.* at §§ 46.107 & 46.109. The Ethical Principles also place an obligation on investigators to seek ethical advice. APA Principles, *supra* note 16, at 637 (Principle 9a).

43. 45 C.F.R. §§ 46.111 (d)(4)-(5) & 46.116-17 (1984); APA Principles, *supra* note 16, at 636 & 638 (Principles 6 & 9d).

44. 45 C.F.R. §§ 46.111(8) and 46.116(8); APA Principles, *supra* note 16, at Prin. 9f.

45. 45 C.F.R. § 46.111(a)(6) & 46.116(5) (1984); APA Principles, *supra* note 16, at 633, 635-36, 638 (Principles 1b, 5, 5b, 5c & 9j).

46. APA Principles, *supra* note 16, at 633, 634-35 (Preamble, Principles 1a & 4). IRBs are forbidden to consider long-range effects of a study in determining whether to approve it. 45 C.F.R. § 46.111(a)(2).

47. APA Principles, *supra* note 16, at 633 (Principle 1a).

48. *Id.*

49. See generally *Socially Sensitive Research: Contemporary Ethical and Professional Dilemmas* (B. Stanley chair) (symposium presented at the meeting of the Am. Psychological Ass'n, Los Angeles, Aug. 26, 1985, to be published in AM. PSYCHOLOGIST).

50. Research involving socially disadvantaged groups may be important to learning ways of alleviating their condition, although it may also result in "blaming the victim" and explaining away their "deficits." See, e.g., W. RYAN, *BLAMING THE VICTIM* (rev. ed. 1976); Levine, *Old People Are Not All Alike: Social Class, Ethnicity/Race, and Sex Are Bases for Important Differences*, in *SOCIAL RESEARCH: SURVEYS AND EXPERIMENTS*, *supra* note 1, at 127; Loo, *Vulnerable Populations: Case Studies in Crowding Research*, in *SOCIAL RESEARCH: SURVEYS AND EXPERIMENTS*, *supra* note 1, at 127.

the other hand, socially sensitive research by definition is such that breaches of confidentiality or careless reporting of findings may result in harm to participants and the classes they represent. When the topic is not only socially sensitive but developing amidst great publicity and intense public interest—even hysteria—the clash of interests (and of ethical principles) becomes especially acute. For neither the public, the groups under study, nor the participants themselves is there likely to be the opportunity to postpone research for a period of sober reflection.

Research on acquired immune deficiency syndrome (AIDS) presents just a situation. To appreciate the conflicts engendered by psychosocial research on AIDS, it is necessary to have some knowledge of the nature and epidemiology of the illness. Four factors have contributed to the sensitivity of research on AIDS.

First, only particular classes of people, most of them already vulnerable to social stigma and even criminal penalties, have been identified as being at risk for AIDS. The groups at highest risk for acquisition of AIDS are gay and bisexual men,⁵¹ and intravenous drug users.⁵² Haitian immigrants, some of whom are illegal aliens, were until recently also considered to be a group at risk for AIDS.⁵³ Thus, the mere identification of participants for research, especially if less than fully confidential, may subject them to harm.⁵⁴ Reporting the results across social groups may serve to exacerbate the stigma already experienced by the groups under study.⁵⁵

A second and related point is that research on AIDS inevitably carries the investigator into highly sensitive and personal areas. As would be suggested by the characteristics of the groups at risk, transmission of AIDS is believed to occur only through exchange of bodily fluids, such as certain sexual contact, sharing of needles for intravenous injections, or sharing of blood during transfusions or pregnancy

51. Centers for Disease Control, *Update: Acquired Immunodeficiency Syndrome - United States*, 34 MORBIDITY AND MORTALITY WEEKLY REP. 245, 246 (1985) [hereinafter cited as CDC]. Gay and bisexual men comprise 73.4 percent of AIDS patients.

52. IV drug users make up 17.0 percent of the AIDS patients. *Id.* at 246.

53. Healthy Haitian-American immigrants are more likely than other Americans to be HTLV-III positive, but it now appears that the risk factors among Haitians are not unique. Therefore, they have been removed as a special risk group. *Id.* at 247. The inclusion of Haitians as a risk group exacerbated political tensions between the United States and Haiti. See Panem, *AIDS, Public Policy and Biomedical Research*, 85 CHEST 416, 417-18 (1984).

54. Hemophiliacs, for example, may become stigmatized because of their risk of acquiring AIDS through contaminated transfusions. Transfusion recipients constitute 1.4 percent of AIDS patients. CDC, *supra* note 51, at 246.

55. See *supra* notes 49 and 50.

(to the fetus).⁵⁶ There is no evidence that transmission can occur through casual skin contact or by airborne, respiratory means.⁵⁷ To understand the mode of transmission fully requires the gathering of data regarding details of sexual practices, drug use, travel, and associations, not only of AIDS patients themselves, but also, their lovers and friends, members of groups at risk, and control groups.⁵⁸ Moreover, to test particular hypotheses about modes of transmission may require some intrusion into privacy simply in obtaining the sample, even before any questions are asked. For example, in one study determining the nature of sexual practices differentiating gay men who were at especially high risk for AIDS, one sample was obtained by stopping men as they left bathhouses and asking them to participate in the study.⁵⁹

Third, AIDS appeared suddenly and has spread rapidly, thus heightening the clamor for rapid acquisition of knowledge. The illness was first identified in 1981 and is thought to have first appeared in the United States in 1979.⁶⁰ By the end of 1984, 7,000 cases had been reported in the United States.⁶¹ The reported incidence of AIDS has been doubling every year, with 40,000 new cases expected by the beginning of 1987.⁶² Although over 75 percent of American AIDS patients were residents of New York, California, Florida, or New Jersey at the time their illness began, AIDS has been reported in forty-five states, the District of Columbia, Puerto Rico, and twenty-one other countries.⁶³ Furthermore, in Africa, heterosexual contact may be a common means of transmission,⁶⁴ thus increasing the possibility of spread from identified risk groups into the general population.

Fourth, the emotion attached to research about AIDS is clearly intensified by the fact that it has a fatal prognosis. AIDS is characterized by severe and apparently irreversible reduction of helper T-cells,⁶⁵ which are very important for the proper functioning of the im-

56. Council on Scientific Affairs, *The Acquired Immune Deficiency Syndrome*, 252 J. A.M.A. 2037, 2040 (1984).

57. *Id.* at 2042.

58. See, e.g., CDC Interview Protocol No. 577 (n.d.).

59. W. Horstman, *Dilemma of Sampling a Hidden Population* (Aug. 25, 1984) (paper presented at the meeting of the Am. Psychological Ass'n, Toronto).

60. Council on Scientific Affairs, *supra* note 56, at 2037.

61. Office of Technology Assessment, *Review of the Public Health Service's Responses to AIDS: A Technical Memorandum 6* (Feb. 1985) [hereinafter cited as OTA].

62. *Id.*

63. Council on Scientific Affairs, *supra* note 56, at 2038.

64. Women, most of whom immigrated from Africa, comprise 40 percent of the patients with AIDS in Belgium. Only 7 percent of the identified AIDS patients in the United States have been women. *Id.* at 2038.

65. Witt & Goldberg, *The National Institutes of Health and Research into the Acquired Immune Deficiency Syndrome*, 98 PUB. HEALTH REP. 312, 313 (1983).

mune system. This deficit in helper T-cells makes one highly susceptible to opportunistic infections with serious, often fatal results.⁶⁶

This combination of factors has led to a virtually unprecedented push toward rapid acquisition and dissemination of research on AIDS,⁶⁷ combined with continuing concern that the process of development of knowledge—particularly breaches of confidentiality—may actually harm participants and the groups they represent.⁶⁸ AIDS patients and groups at risk are thus caught in a dilemma in which they have a profound desire for information that may contribute to prevention or treatment of AIDS, but also a particularly acute need for protection of privacy. Beyond these personal conflicts, the need to gather information that may be useful in protecting the public health may clash directly with potential participants' privacy. Protecting the public may also make participants vulnerable to harm. Thus, AIDS research presents acute conflicts of interest and principle, which make it a useful example for study of problems of the law and ethics of research.

B. Recent Developments in Knowledge about AIDS

The priority placed on research on AIDS has in fact resulted in rapid development of knowledge about the syndrome, although many important unanswered questions remain.⁶⁹ The most significant development has been the discovery of a retrovirus⁷⁰ that is believed to be the causal agent involved in AIDS. Researchers at the National Cancer Institute isolated the retrovirus HTLV-III (human T-cell lymphotropic virus) from the blood of a number of patients with AIDS

66. Three fourths of the AIDS patients diagnosed before July, 1982, had died by 1984. CDC, *supra* note 51, at 337. The two most common opportunistic infections that affect AIDS patients are *Pneumocystis carinii* pneumonia (PCP) and Kaposi's sarcoma (KS).

67. Then Assistant Secretary of HHS Edward Brandt, Jr. requested major journals to expedite review of research on AIDS and announce accepted findings prior to their publication. Batchelor, *AIDS: A Public Health and Psychological Emergency*, 39 AM. PSYCHOLOGIST 1279, 1281 (1984). Assistant Secretary Brandt also ascribed top priority status to work on AIDS. Brandt, *The Public Health Service's Number One Priority*, 98 PUB. HEALTH REP. 306, (1983). However, the Office of Technology Assessment has characterized the increased resources applied to research on AIDS as following from Congress's goading and not from a commitment in HHS, especially at the Department level. See generally OTA, *supra* note 61.

68. See *infra* notes 106-41 and accompanying text.

69. The obvious steps still missing are the development of a vaccine and an effective treatment. OTA, *supra* note 61, at 5-6.

70. Retroviruses are "[v]iruses that contain RNA, not DNA, and that produce a DNA analog of their RNA through the production of an enzyme known as 'reverse transcriptase.' The resulting DNA is incorporated in the genetic structure of the invaded cell, in a form referred to as the 'provirus.'" *Id.* at 147-48.

or AIDS-related condition (ARC).⁷¹ In serologic surveys, antibodies reactive with HTLV-III antigens have been found in 68 to 100 percent of patients with AIDS, 84 to 100 percent of patients with AIDS-related conditions, 22 to 65 percent of gay men, 87 percent of intravenous drug users in one program, 56 to 72 percent of persons with hemophilia A, and 35 percent of female sexual partners of men with AIDS.⁷² Fewer than 1 percent of persons outside identified risk groups are seropositive for HTLV-III antibodies.⁷³

Although testing for the presence of antibodies against HTLV-III is useful for the screening of blood and plasma donations,⁷⁴ and as an instrument for more focused research on AIDS,⁷⁵ the Public Health Service has emphasized that "*the antibody test is NOT a test for AIDS*,"⁷⁶ an opinion shared by the American Medical Association's Council on Scientific Affairs.⁷⁷ The prognosis for apparently healthy seropositive persons is uncertain. According to the Centers for Disease Control, preliminary studies show that 5 to 20 percent of seropositive gay men develop AIDS within two to five years, but this finding may not be applicable to other risk groups.⁷⁸ The ambiguous meaning of antibody test results is illustrated by the possible interpretations

71. Broder & Gallo, *A Pathogenic Retrovirus (HTLV-III) Linked to AIDS*, 311 NEW ENG. J. MED. 1292 (1984). See also Gallo, Salahuddin & Popovic, *Frequent Detection and Isolation of Cytopathic Retroviruses (HTLV-III) from Patients with AIDS and At Risk for AIDS*, 224 SCI. 500 (1984); Popovic, Sarngadharan, Read & Gallo, *Detection, Isolation, and Continuous Production of Cytopathic Retroviruses (HTLV-III) from Patients with AIDS and Pre-AIDS*, 224 SCI. 497 (1984); Sarngadharan, Popvic, Bruch, Schupbach & Gallo, *Antibodies Reactive with Human T-Lymphotropic Retroviruses (HTLV-III) in the Serum of Patients with AIDS*, 224 SCI. 506 (1984); Schupbach, Popovic, & Gilden, *Serologic Analysis of a Subgroup of Human T-Lymphotropic Retroviruses (HTLV-III) Associated with AIDS*, 224 SCI. 503 (1984). AIDS prodrome, also known as pre-AIDS or the lymphadenopathy syndrome, is characterized by "unexplained chronic lymphadenopathy, nonspecific constitutional symptoms, and in vitro immunologic abnormalities." Council on Scientific Affairs, *supra* note 56, at 2037. No precise estimates of what proportion of persons with these symptoms will progress to having AIDS can be made at this time. *Id.* at 2037.

72. Centers for Disease Control, *Provisional Public Health Service Inter-Agency Recommendations for Screening Donated Blood and Plasma for Antibody to the Virus Causing Acquired Immune Deficiency Syndrome*, 34 MORBIDITY & MORTALITY WEEKLY REP. 5, 5 (1985) [hereinafter cited as CDC Recommendations].

73. *Id.*

74. See generally *id.*

75. OTA, *supra* note 61, at 5-6 & 16-26.

76. Letter from Frank E. Young, Comm'r, Food & Drugs Admin., to physicians 2 (n.d.).

77. Council on Scientific Affairs, *supra* note 56, at 2039.

78. CDC Recommendations, *supra* note 72, at 5. This conclusion by the CDC is highly speculative, given that there has been under two years of history of HTLV-III testing.

offered by a task force of the Massachusetts Department of Public Health:

[A] positive test may indicate *any* of the following:

1. a test is a false positive
2. a person has been infected and is protected
3. a person may harbor the virus and remain healthy
4. a person may be ill with AIDS

Similarly, a negative test may mean

1. a person has not been exposed and is not infected
2. a person may be in early stages of infection or may not be able to produce antibody to the infection
3. a test is a false negative.⁷⁹

The isolation of HTLV-III as a probable causal agent and the availability of a test for the presence of antibodies to it are clearly important developments. However, the existence of the test has resulted in its own ethical problems. First, because of the high rate of seropositivity in risk groups, there is the potential for misuse of the test to, for example, screen for homosexuality. It is not difficult to imagine blood samples gathered in employment physicals being used surreptitiously for the purpose of employment discrimination. Similarly, there may be threats to privacy from registries of seropositive persons maintained by blood banks.⁸⁰ Second, the spectre has been raised of persons in risk groups seeking to donate blood in order to find out whether they were seropositive and, therefore, actually heightening the risk of contamination of the blood supply. Partially for that reason, centers have been established in many localities solely for the purpose of conducting tests for HTLV-III antibodies.⁸¹ Third, in view of the uncertainty associated with interpretation of the test, informing people as the results of their tests might cause undue distress or, if negative, unwarranted complacency.⁸²

Each of these issues has affected research on AIDS. First, there are problems of maintenance of confidentiality of antibody test results. Second, persons may seek to participate in studies on AIDS in order to have their blood tested. Participation in such a situation could be perceived as less than fully voluntary.⁸³ Third, there is a question of whether test results should be withheld from research participants. Because of the potential harm from breach of confidentiality and the distress engendered by positive results, gay organizations

79. *Massachusetts Acts to Further Protect the Blood Supply 2* (Feb. 14, 1985) (news release from Mass. Dep't. of Pub. Health) [hereinafter cited as *Massachusetts*].

80. OTA, *supra* note 61, at 48-49.

81. See, e.g., *Massachusetts*, *supra* note 79, at 3.

82. See, e.g., Cunningham, *AIDS Antibody Test Ignores Impact on High-Risk Groups*, APA MONITOR, Mar. 1985, at 1, 8-9.

83. The participant would be participating in order to obtain a perceived benefit, no matter what the risks involved.

have generally argued that persons should avoid the antibody test,⁸⁴ which might result in a chilling of research. Even if individuals consent to the test, it is arguable that the principle of beneficence requires the withholding of this information which is undoubtedly disturbing but of questionable benefit to them.⁸⁵ This argument is given greater credence by evidence that people generally have difficulty in weighing accurately such base rate information as the rates of persons in risk groups who have seropositivity and of seropositive persons who develop AIDS.⁸⁶

However, both the Department of Health and Human Services⁸⁷ and the APA Committee for the Protection of Human Participants in Research (CPHPR)⁸⁸ have concluded that test results should be available to participants. Arguing that the principle of respect for persons and, therefore, their autonomy demanded informing participants of test results, CPHPR issued the following guideline:

It is presumptuous of investigators to withhold potentially bad news which may be important in future decisions by participants;⁸⁹ it is obligatory in such instances to give *more* information, not less. Participants need to be made aware of the uncertainty of the meaning of particular findings. Indeed, were there certainty, the study would not need to be conducted.

In providing such information, psychologists should use their own and their colleagues' knowledge about ways of presentation of information so as to maximize the probability that participants will have an understanding of, for example, the application of base rates to a calculation of risk.⁹⁰

CPHPR also acknowledged that the principle of beneficence requires "careful attention . . . to emotional responses to the informa-

84. Cunningham, *supra* note 82, at 1.

85. Cf. C. LIDZ, A. MEISEL, E. ZERUBAVEL, M. CARTER, R. SESTAK & L. ROTH, INFORMED CONSENT: A STUDY OF DECISION MAKING IN PSYCHIATRY 18-19 (1984) (discussing therapeutic privilege) [hereinafter cited as INFORMED CONSENT].

86. For overviews of the literature on foibles in legally relevant decision making, see Saks & Kidd, *Human Information Processing and Adjudication: Trial by Heuristics*, 15 LAW & SOC'Y REV. 123 (1980-81); Thompson, *Psychological Issues in Informed Consent*, in 3 MAKING HEALTH CARE DECISIONS app. H (1983) (background paper submitted to President's Comm'n for the Study of Biomed. & Behavioral Research). See generally L. BOURNE, R. DOMINOWSKI & E. LOFTUS, COGNITIVE PROCESSES (1979); R. HOGARTH, JUDGMENT AND CHOICE (1980); Tversky & Kahneman, *Judgment under Uncertainty: Heuristics and Biases*, 185 SCI. 1124 (1973).

87. Office for Protection from Research Risks, Nat'l Inst. of Health, Guidance for Institutional Review Boards for AIDS Studies 3 (Dec. 26, 1984) [hereinafter cited as OPRR].

88. Comm. for the Protection of Human Participants in Research, *Ethical Issues in Research on AIDS*, APA MONITOR, July 1985, at 26, col. 4-5 [hereinafter cited as CPHPR].

89. In the absence of knowledge about the meaning of HTLV-III, seropositive persons may want to take some precautionary steps (e.g., avoiding pregnancy). CDC Recommendations, *supra* note 72, at 11.

90. CPHPR, *supra* note 88, at 26, col. 4-5.

tion. Research on AIDS demands more than perfunctory counseling."⁹¹ Investigators are obligated to ensure that concerns stimulated by the study are alleviated.⁹²

C. The Significance of Psychosocial Research on AIDS

The issues surrounding feedback on the results of antibody tests suggest the obvious: perceiving that one is at risk for AIDS, actually being at risk, having AIDS itself or an AIDS-related condition (ARC),⁹³ or being responsible for the care of people in one of these groups⁹⁴ is likely to engender significant emotional reactions. Unsurprisingly, depression is a common correlate of AIDS,⁹⁵ and there are anecdotal reports of increased stress levels in risk groups since the existence of AIDS became known.⁹⁶ Response to these psychological needs is important in itself and should be a part of treatment plans for AIDS patients and community education efforts.⁹⁷ Research is needed to indicate the particular psychological responses elicited by AIDS and to demonstrate ways in which counseling and education can be conducted most effectively.⁹⁸

91. *Id.* at 26, col. 5.

92. *Id.* See APA Principles, *supra* note 16, at 638 (Principle 9i.)

93. See *supra* note 71. The CDC recognizes an *AIDS-related complex*:

A variety of chronic but nonspecific symptoms and physical findings that appear related to AIDS, which may consist of chronic generalized lymphadenopathy, recurrent fevers, weight loss, minor alterations in the immune system, and minor infections. Some persons with AIDS-related complex may develop full-blown AIDS, while in others, the condition may represent the height of clinical illness in reaction in infection with HTLV-III. AIDS-related complex is sometimes known as "pre-AIDS."

OTA, *supra* note 61, at 145-46.

94. See Furstenberg & Olson, *Social Work and AIDS*, 9(4) SOC. WORK IN HEALTH CARE 45, 56-57 (1984); Morin & Batchelor, *Responding to the Psychological Crisis of AIDS*, 99 PUB. HEALTH REP. 4, 8-9 (1984); Polan, Hellerstein, & Amchin, *Impact of AIDS-Related Cases on an Inpatient Therapeutic Milieu*, 36 HOSP. & COMMUNITY PSYCHIATRY 173 (1985).

95. See Dilley, Ochitill, Perl & Volbering, *Findings in Psychiatric Consultations with Patients with Acquired Immune Deficiency Syndrome*, 142 AM. J. PSYCHIATRY 82 (1985); Forstein, *The Psychosocial Impact of the Acquired Immune Deficiency Syndrome*, 11 SEM. IN ONCOLOGY 77 (1984); Furstenberg & Olson, *supra* note 94, at 49-52; Morin, Charles, & Malyon, *The Psychological Impact of AIDS on Gay Men*, 39 AM. PSYCHOLOGIST 1288, 1288-89 (1984); Perry & Tross, *Psychiatric Problems of AIDS Inpatients at the New York Hospital: Preliminary Report*, 99 PUB. HEALTH REP. 200 (1984).

96. Forstein, *supra* note 95, at 80-81; Morin, Charles & Malyon, *supra* note 95, at 1290-93.

97. See, e.g., Forstein, *supra* note 95; Furstenberg & Olson, *supra* note 94; Goulden, Todd, Hay & Dykes, *AIDS and Community Supportive Services: Understanding and Management of Psychological Needs*, 1984 MED. J. AUSTR. 582; Morin, Charles & Malyon, *supra* note 95.

98. See, e.g., Coates, Temoshok & Mandel, *Psychosocial Research Is Essential to Understanding and Treating AIDS*, 39 AM. PSYCHOLOGIST 1309 (1984).

Perhaps less obviously, behavioral research may be crucial in understanding the transmission of AIDS and some aspects of the disease process itself. First, psychological research is necessary to understand the behavioral modes of transmission.⁹⁹ Such epidemiological research has been an important first step to identification of the nature of the agent involved in the transmission of AIDS.¹⁰⁰ It also may hold the key to minimization of risk among affected groups.¹⁰¹ Second, psychological co-factors may explain a substantial proportion of the variance in the timing of acquisition of AIDS, or whether exposed individuals become ill at all. The study of psychoneuroimmunology¹⁰² may provide clues to the mechanisms of immunosuppression in AIDS.¹⁰³ Third, AIDS sometimes is accompanied by organic brain syndromes, which themselves are serious conditions.¹⁰⁴ The relationship between immunosuppression and central nervous system involvement bears further investigation. Fourth, psychosocial investigation may be useful in identifying effective strategies of health education and medical intervention.¹⁰⁵ Among the topics that deserve further study are issues in fostering lifestyle change (e.g., encouragement of "safe sex"), reducing delay in seeking treatment, and increasing compliance with treatment plans.

99. Martin & Vance, *Behavioral and Psychosocial Factors in AIDS: Methodological and Substantive Issues*, 39 AM. PSYCHOLOGIST 1303, 1304-05 (1984).

100. Epidemiologic studies are particularly likely to give clues to the co-factors involved in the development of AIDS. OTA, *supra* note 61, at 20.

101. Identification of co-factors and behaviors particularly potent in the transmission and acquisition of AIDS may give clues to behavior change strategies that will aid in its prevention. Coates, Temoshok & Mandel, *supra* note 98, at 1312. *See also* OTA, *supra* note 61, at 49-51 (discussing the role of public education for gay men and IV drug users).

102. Psychoneuroimmunology is the study of the relationship between psychological factors (e.g., stress) and immune functioning. *See, e.g.*, PSYCHONEUROIMMUNOLOGY (R. Ander ed. 1981); Maier & Laudenslager, *Stress and Health: Exploring the Links*, 19(8) PSYCHOLOGY TODAY 44 (1985).

103. *See, e.g.*, Coates, Temoshok & Mandel, *supra* note 98, at 1311; Martin & Vance, *supra* note 99, at 1305-06. *But see* OTA, *supra* note 61, at 42-44 (Public Health Service has funded some studies of psychological co-factors in AIDS, but has failed to give much attention to this area).

104. *See generally* Dilley, *supra* note 95; Kermani, Drob & Alpert, *Organic Brain Syndrome in Three Cases of Acquired Immune Deficiency Syndrome*, 25 COMPREHENSIVE PSYCHIATRY 294 (1984); Nurnberg, Prudic, Fiori & Freedman, *Psychopathology Complicating Acquired Immune Deficiency Syndrome (AIDS)*, 141 AM. J. PSYCHIATRY 95 (1984); Perry & Tross, *supra* note 95.

105. *See supra* note 101.

III. SPECIAL PROBLEMS IN PSYCHOSOCIAL RESEARCH ON AIDS

A. Privacy

1. Intrusiveness

Examination of the nature and epidemiology of AIDS and the range of psychosocial research on the illness makes clear the potential threats to privacy involved in such research. Privacy entails recognition of "zones" subsumed within boundaries of the person.¹⁰⁶ Therefore, respect of persons demands respect for privacy.¹⁰⁷ AIDS research implicates two forms of privacy: control of personal information, and control over one's body and mind.¹⁰⁸ As already noted,¹⁰⁹ AIDS research inherently involves some intrusiveness in that it generally requires inquiry into topic areas, such as sexual practices, which are almost universally recognized as personal and sensitive. When selection for the study is based on private behavior (e.g., a potential participant's sexual orientation), mere identification as a potential participant involves some cost in privacy. Moreover, where the study focuses on responses to AIDS, participation may involve intrusion into private thoughts and invoke some distress that would not otherwise have occurred.¹¹⁰

In order to protect privacy, participants' control over personal information should be maintained as much as possible. Such a general rule is obviously consistent with the principle of respect for persons and their autonomy; it is also consonant with the principle of beneficence insofar as intrusions upon privacy have adverse psychological effects.¹¹¹ In keeping with the Ethical Principles of Psychologists, CPHPR issued the following guidelines for research on AIDS:

In general, researchers should minimize the intrusiveness of studies insofar as possible. Whenever possible, data should be derived from clinical interviews and archives which would already be collected. Under most circumstances, potential participants should be contacted only after they have volunteered

106. Privacy includes control over one's body, personal space, and personal information. Melton, *Minors and Privacy: Are Legal and Psychological Concepts Compatible*, 62 NEB. L. REV. 455, 458-60 (1983) (and cites therein). A somewhat different psychological conceptualization has been offered by Laufer & Wolfe, *Privacy as a Concept and Social Issue: A Multidimensional Development Theory*, 33(3) J. SOC. ISSUES 22 (1977).

107. Melton, *supra* note 106, at 460.

108. *See supra* note 106.

109. *See supra* notes 56-59 and accompanying text.

110. Some distress may be evoked in thinking about AIDS itself, sexual preference, experiences of loss and powerlessness, and so forth. *See, e.g.*, Joseph, Emmons, Kessler, Wortman, O'Brien, Hocker & Schaefer, *Coping with the Threat of AIDS: An Approach to Psychosocial Assessment*, 39 AM. PSYCHOLOGIST 1297 (1984); Morin, Charles & Malyon, *supra* note 95.

111. *See* APA Principles, *supra* note 16, at 638 (Principle 9g).

directly, or permission for contact has been obtained by an appropriate intermediary who is the source for identification of the participant (e.g., personal physician; the AIDS patient, when the population to be studied includes patients' lovers or acquaintances). When more intrusive procedures appear necessary for the conduct of a study, the researcher is especially obligated to consider and seek advice about the merits of the study in the face of the invasion of privacy (Principles 9 and 9a). The researcher should warn potential participants when the content of an interview or questionnaire may be disturbing (Principles 9d and 9f) and permit them to refrain from participating or to withdraw if they choose (Principle 9g). . . . [C]areful debriefing and follow-up should be undertaken to identify and prevent or alleviate stressful effects of participation (Principles 9g and 9i).¹¹²

The need to minimize sensitive research procedures (e.g., interviewing about highly personal matters) is especially acute when participation is, or appears to be, compelled. State reporting requirements at present extend only to basic medical and demographic information, although some sensitive information (e.g., sexual preference) is likely to be included.¹¹³ It is conceivable, however, that if believed to be necessary to establish the cause or mode of transmission of the illness, production of much more detailed personal information would be compelled under the state's police power to protect the public health.¹¹⁴ Even if a response is not legally mandated, requests for such information by state or federal authorities may be perceived as legal requirements, especially if some information is required. Interview protocols have been developed by the federal Centers for Disease Control (CDC) for surveillance of AIDS patients.¹¹⁵ These in fact include detailed questions about sexual experiences, drug and alcohol use, medical history, travel history, and so forth.¹¹⁶ Care should be taken to ensure that participants understand when they are free not to answer questions.¹¹⁷ When in fact some production of information is legally compelled, the invasion of privacy should be no greater than is necessary to meet the state's compelling interest in the preservation of public health.¹¹⁸ Under such circum-

112. CPHPR, *supra* note 88, at 26, col. 3.

113. CDC's case reporting form, OMB No. 0920-0008 (rev. Apr. 1983), includes questions about sexual orientation, sexual relationships, prison history, and IV drug users.

114. *Cf. Jacobsen v. Mass.*, 197 U.S. 11 (1905).

115. In public health jargon, surveillance means the interview and follow-up of patients in order to determine the pattern of transmission of an illness. Although it does involve intrusion upon privacy, it need not imply the careful scrutiny that the term connotes in popular usage. See Novick, *At Risk for AIDS: Confidentiality in Research and Surveillance*, IRB Nov.-Dec. 1984, at 10. (1984).

116. See *supra* note 58.

117. See APA Principles, *supra* note 16, at 638 (Principle 9f) ("The obligation to protect . . . [the] freedom [to decline to participate] requires careful thought and consideration when the investigator is in a position of authority or influence over the participant").

118. CPHPR, *supra* note 88, at 26, col. 3.

stances, researchers bear a special obligation to consult with colleagues and the public about whether the need for information is so great in a particular sense to require participation.¹¹⁹ Researchers' ethical obligations are not absolved by the imprimatur of legal or public health authorities.¹²⁰

2. Confidentiality

Concerns about privacy of information do not end, of course, with the question of how much information to solicit or compel. The participant who has produced personal information retains an interest in controlling access to the information. Beyond the basic principle of maintenance of individuals' autonomy in decision making in private matters,¹²¹ the principle of beneficence requires that researchers make an effort to shield participants from harm that might potentially result from their participation.¹²² Where the content is sensitive, preservation of confidentiality becomes critical to such protection. As one court put it: "Revelations [to psychologists] often concern the most intimate and embarrassing details of a patient's life, and their public exposure may well strip him of much of his own sense of human dignity."¹²³

The typical insult to privacy entailed in disclosure of identifiable research data without the consent of the participant is exacerbated in AIDS research by the adverse social, legal, and economic consequences that may result from breaches of confidentiality. There is ample evidence for stigma resulting from the diagnosis itself. Despite the available knowledge about the modes of transmission of AIDS, health care staff have been known to tend to AIDS patients only while wearing a mask, gown, and gloves, to refuse to draw or test their blood, and to avoid touching them.¹²⁴ The Secretary of Health and Human Services, Margaret Heckler, even found it necessary to send a memorandum to Social Security employees admonishing them to assist clients with AIDS, and reassuring the employees of the lack of risk in handling clients' papers or talking with them.¹²⁵ Individuals

119. *Id.* at 26, col. 2.

120. APA Principles, *supra* note 16, at 634, 638 (Principles 3d & 9c); CPHPR, *supra* note 88, at 26, col. 2.

121. *See supra* note 37 and accompanying text. *See also* APA Principles, *supra* note 16, at 638 (Principles 9d & 9f) (noting autonomy of participant in deciding whether to participate); Melton, *supra* note 106, at 488-89 (noting psychological and ethical significance of control of access to personal information).

122. *See supra* note 38 and accompanying text. *See also* APA Principles, *supra* note 16, at 638 (Principle 9g).

123. *Lora v. Board of Education*, 74 F.R.D. 565, 571 (E.D.N.Y. 1977).

124. *AIDS: Fear and Loathing*, 1983 EMERGENCY MED. 157.

125. Memorandum from Margaret Heckler to all Soc. Sec. Admin. employess (July 7, 1983).

with AIDS have been fired from their jobs, evicted from their homes, denied dietary and nursing services in hospitals or admission at all, and even refused mortician services after death.¹²⁶ Thus, persons with AIDS often must face shunning by others because of their fear of catching AIDS or their inability to deal with people who have a potentially terminal illness. The social isolation that often results when acquaintances know of the diagnosis makes coping with a serious illness more difficult.¹²⁷ Furthermore, because of the generalized, irrational nature of fear of AIDS, some stigma may accrue from mere participation in a study about AIDS, even if one does not actually have the illness.

Disclosure of research data, or simply the fact of participation, can also be harmful because of the stigma to which risk groups are already vulnerable. Gay men are widely subjected to discrimination.¹²⁸ Some prominent spokespersons for the religious right have denounced homosexuality as immoral and have gone so far to say that gay persons are a threat to society who deserve to die.¹²⁹ The public image of IV drug users is that they are skid-row addicts who will engage in whatever criminal behavior is necessary to maintain their habit.¹³⁰ Haitian Americans find racial discrimination against them exacerbated by cultural and linguistic differences, and the widespread publicity about the influx of illegal immigrants from Haiti.¹³¹

All three of the groups initially considered to be the primary groups at risk for AIDS are also vulnerable to legal sanctions. Gay men face at least the threat of criminal prosecution in twenty-five states where homosexual acts are still crimes.¹³² For IV drug users, their drug use is illegal throughout the United States, as are the associated activities of possession and sale of drugs and drug paraphernalia.¹³³ Some Haitian Americans are illegal immigrants, who lack

126. Drake, *As Baffling Illness Spreads, So Does the Concern*, Philadelphia Inquirer, Feb. 13, 1983, at 1. See also Kang, *A Hard Look: AIDS Victims Seek Help in Court*, San Francisco Examiner, Sept. 10, 1983, at A-1; Pimsleur, *Mayor Furious Over 'Dumping' of AIDS Victim*, San Francisco Chron., Oct. 8, 1983, at 1.

127. Nelson, Maxey & Keith, *Are We Abandoning the AIDS Patient?*, 1984 RN 18.

128. See generally GAY MEN: THE SOCIOLOGY OF MALE HOMOSEXUALITY (M. Levine ed. 1979); G. GOODMAN, G. LAKEY, J. LASHOF & E. THORNE, NO TURNING BACK: LESBIAN AND GAY LIBERATION FOR THE 80's (1983).

129. A. Novick, Memo on Ethical Aspects of AIDS Research (1984) (unpublished manuscript).

130. See generally P. BARIDON, ADDICTION, CRIME, AND SOCIAL POLICY (1976); D. BEL-LIS, HEROIN AND POLITICIANS: THE FAILURE OF PUBLIC POLICY TO CONTROL ADDICTION IN AMERICA (1981); ADDICTION (P. Bourne ed. 1974); C. LIDZ & A. WALKER, HEROIN, DEVIANCE, AND MORALITY (1980).

131. A. Novick, *supra* note 129, at 2.

132. RIGHTS OF GAY PEOPLE: THE REVISED EDITION OF THE BASIC ACLU GUIDE TO A GAY PERSON'S RIGHTS 131 (1984).

133. A. Novick, *supra* note 129, at 2.

many civil rights and are at high risk of imprisonment, deportation, and/or loss of employment.¹³⁴

Thus, when identifying information is released to legal authorities, employers, health care workers, and others, participants in AIDS research may be harmed socially and legally. Furthermore, harm may result if identifying information about participants is released by researchers to the CDC or other public health agencies for surveillance purposes. If AIDS were to be considered a communicable disease with such a grave risk for public health that quarantine for AIDS patients would be warranted,¹³⁵ CDC would be in possession of the names of many people with AIDS through their surveillance records. Presumably, these persons would then be found and confined. This risk of infringement of liberty in the name of public health may also apply to those individuals who have tested positive for HTLV-III antibodies and are considered at greater risk for developing AIDS. The potential conflict of roles for the CDC of research and enforcement led some members of a task force convened by the Hastings Center to argue that data collected for the government in such a sensitive context should be collected and stored by private agencies.¹³⁶

The potential for harm may extend beyond participants to their lovers and friends. Although not justified by current knowledge, it is conceivable that states may make seropositivity for HTLV-III antibodies a "reportable disease." If a researcher were to report such a finding about participants, they could be required to list "contacts" they have had, as some mandated reporting statutes for venereal disease require.¹³⁷ The contacts themselves then would be compelled to submit to an interview and medical examination.

Not only the participants and their acquaintances, but society as a whole, ultimately may be harmed by breaches of confidentiality in research on AIDS. If potential participants perceive a risk of involuntary disclosure of their data, they may be deterred from engaging in research, and researchers may be chilled from pursuing study of socially sensitive topics. For the short term, the search for a vaccine and a cure for AIDS would be frustrated. For a long term, the pursuit of socially sensitive knowledge more generally might be chilled, with adverse consequences for human welfare.¹³⁸

The simplest answer to the problems of confidentiality, short of

134. *Id.*

135. A Novick, A Consideration of the Role of Quarantine for Persons Carrying the AIDS Agent 1 (July 1984) (unpublished manuscript).

136. Boruch, *Should Private Agencies Maintain Federal Research Data*, IRB Nov.-Dec. 1984 at 8.

137. See 42 U.S.C. § 247c(c) (1982).

138. See *Andrews v. Eli Lilly & Co.*, 97 F.R.D. 494 (N.D. Ill. 1983); *Lampshire v. Proctor & Gamble Co.*, 94 F.R.D. 58 (N.D. Ga. 1982).

failing to conduct research at all, would be to keep no identifiable data.¹³⁹ However, as a practical matter, deletion of sufficient personal information to prevent "deductive disclosures" of participants' identity may be impossible in many instances.¹⁴⁰ Assuming arguendo, though, that the identity of participants can be sufficiently disguised to make it impossible to match participant and data, the solution may be undesirable. Although participants in AIDS research have a clear interest in privacy, they also may be harmed by *failing* to keep identifiable information. The Hastings Center task force on AIDS research noted several instances in which it is essential to keep identifiers: "(a) the researcher may need to inform a research subject about a medical condition requiring treatment; (b) the researcher requires linking one set of data with other sets; (c) the researcher requires linking information gathered at different times; or (d) the researcher requires verifying the reliability of the data."¹⁴¹

The first of these purposes is unlikely to be related to the research design itself.¹⁴² Rather, the need to inform about medical conditions is more likely to arise from an ethical demand to promote the welfare of participants.¹⁴³ It is important to note in that regard that, in a rapidly developing area like AIDS research, it may not be possible to predict when information will be of importance. For example, a particular subgroup may appear, on analysis of the data from the instant study or other research, to be at special risk or of special significance in understanding the illness. Without identifiers, it would be impossible to contact the particular participants to request their involvement in further study, or to inform them of precautions or treatments that research suggests may be effective in their cases.

The remaining points mentioned by the Hastings Center group are methodological. Certain types of research require retention of identi-

139. See OPRR, *supra* note 87, at 3.

140. Accidental deductive disclosures may be more common in AIDS research than most other research because of the small number of available participants. There may be only one female I.V. drug user, aged 19, with one child in a particular program or community. However, there are methods that can be used to control this type of disclosure, such as controlling access to lists of respondents, microaggregation, and construction of crude report categories. R. BORUCH & J. CECIL, ASSURING THE CONFIDENTIALITY OF SOCIAL RESEARCH DATA 274 (1979).

141. Bayer, Levine & Murray, *Guidelines for Confidentiality in Research on AIDS*, IRB Nov.-Dec. 1984, at 1, 2-3.

142. An exception would be if the study is designed to test an early intervention program. *E.g.*, what are the effects of a health education program on seropositive but apparently health individuals?

143. There is, of course, an ethical dilemma involved. Is it better to inform participants about a condition that has been identified in the course of a study and possibly upset them, when they might use the information to seek treatment to correct the problem? Or is it better to avoid upsetting participants who, after all, did not seek assessment? See APA, COMMENTARY ON ETHICAL PRINCIPLES, *supra* note 6, at 61-62.

fiers. Notably, longitudinal research¹⁴⁴ cannot be performed without the maintenance of identifiers, at least for the length of time covered by the study. Longitudinal research is important in understanding the course of AIDS. For example, the meaning of seropositivity to HTLV-III antibodies is unlikely to be known until there is adequate follow-up across time.¹⁴⁵ Similarly, to use a psychosocial example, longitudinal research would be especially helpful in determining whether immunosuppression is correlated with stress. Thus, information derived from longitudinal studies about the precise timing of development of AIDS may provide important clues about the processes underlying the illness.

In short, the interests of both society and the participants themselves in confidentiality are mixed. Although failure to protect confidentiality adequately may adversely affect both the pursuit or knowledge about AIDS and the welfare of participants, failure under all circumstances to keep identifiable information also may deter development of knowledge crucial to understanding AIDS. Such de facto prohibition of longitudinal research and combination of data sets¹⁴⁶ would obviously be detrimental to the welfare of society and the participants.

The one clear guideline that can be stated about keeping identifiable information is that, in order for participants' consent to the research to be valid, investigators are legally and ethically obligated to clarify the limits of confidentiality before potential participants agree to participate.¹⁴⁷ If the researcher plans to keep identifiable data, potential participants must be informed of the foreseeable risks and benefits of doing so, and given a choice of whether they want their data stored.¹⁴⁸ Moreover, investigators are ethically obligated to take whatever steps are necessary prior to, during, and after the study to minimize threats to the confidentiality of the data.

144. Longitudinal research is the term for studies in which participants are observed at several points in time.

145. The incubation period for AIDS is apparently quite lengthy. To understand the meaning of seropositivity will require following individuals who are HTLV-III positive or negative for extended periods of time. The latency period for development of the illness typically may be more than two years. See Eyster, Goedert, Sarngadharan, Weiss, Gallo & Blattner, *Development and Early Natural History of HTLV-III Antibodies in Persons with Hemophilia*, 253 J. A.M.A. 2219 (1985).

146. It is not always possible to foresee when combination of data sets would be useful. Two investigators may be working independently on a problem or a population, in which it turns out that they might test intriguing findings by sharing data.

147. See, e.g., 45 CFR § 46.116(a)(5); APA Principles, *supra* note 16, at 635, 638 (Principles 5 & 9j).

148. Bayer, *supra* note 141, at 3; CPHPR, *supra* note 88, at 26, col. 4.

B. Reporting the Results

The possibility of involuntary disclosure of the data raises another ethical and legal issue: when and how the results of a study on AIDS should be reported. If an investigator is compelled to disclose data before a study is completed, not only is there likely to be harm from the breach of confidentiality per se, but the study may be "spoiled."¹⁴⁹ Besides the costs to society and the researcher of not permitting the completion of the study, there may be misleading impressions left by the preliminary, incompletely analyzed data. Society as a whole or particular groups may be led erroneously into panic or complacency, with corresponding errors in policy.¹⁵⁰ Results also may be used to ostracize groups unfairly, a high risk in AIDS because affected groups may be blamed for their vulnerability and subjected to even more stigma.¹⁵¹

Ethical dilemmas related to the timing and content of disclosure of the results of a study are not limited to instances in which the production of data is compelled, whether in raw or summarized form.¹⁵² Indeed, the issue arises even before a study begins. Institutional review boards (IRBs), the primary legally authorized regulatory bodies for research with human participants,¹⁵³ are barred from consideration of "possible long-term effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy)"¹⁵⁴ in determining the acceptability of a proposed study. Such

149. The necessity of making the study public may prejudice potential participants to behave in ways that they think are consistent with the results that should be obtained. Interruption of data collection to collate recordings consistent with a subpoena, for example, also may necessitate a change in the design of the study.

150. Forced disclosure of research information can be very damaging to a researcher and the public. If disclosure is sought before data are complete and properly analyzed, it could result in misleading findings. Inaccuracies in reports could cause harm to the public by giving them misinformation, and to the researcher by damaging her standing in the academic community or jeopardizing her career. At the least it would endanger her ability to obtain participants for sensitive research. See generally Matherne, *Forced Disclosure of Academic Research*, 37 VAND. L. REV. 585 (1984).

151. Because of the prejudices already present toward the groups at risk, there may be a tendency to misinterpret results that have not been presented with care. The characterization of AIDS by some groups as the "gay plague," and their desire to quarantine gay men, may lead them to publicize partial results in misleading fashion. See Miller, *Today's Scarlet Letter: Public Health and Civil Rights in the Age of AIDS*, Boston Phoenix, Mar. 26, 1985, § 2, at 1; Payne & Risch, *The Politics of Aids*, SCI. FOR THE PEOPLE, Sept.-Oct. 1984, at 17.

152. Obviously a requirement to disclose summarized data prematurely poses less threat to participants' privacy than compelled disclosure of raw data. However, problems remain of the researcher's loss of property interest and the public's being potentially misled.

153. 45 C.F.R. § 46.109 (1984).

154. *Id.* at § 46.111.

prohibition of IRB consideration of social and political factors in the desirability of research is probably necessary to academic freedom.¹⁵⁵ Investigators are, however, ethically required to weigh the potential risks and benefits—including those attached to reporting the results—in deciding whether to conduct a study.¹⁵⁶

The same sort of conflict arises when the study is underway. If preliminary data suggest an important development in knowledge about AIDS, should the researcher report these results before the study is completed? The researcher may feel public pressure (sometimes in the form of journalists' clamor for information)¹⁵⁷ to release results prematurely, and substantial self-interest in maximizing the probability of being first to report a particular phenomenon of great public and professional interests. AIDS has in fact been the subject of extraordinarily rapid review for grants and publication, with announcement of findings even prior to publication.¹⁵⁸

CPHPR emphasized the need for caution in deciding whether to release results voluntarily prior to conclusion of a study and peer review:

In the midst of these pressures [for premature disclosure of results], it is important that researchers not lose sight of the social sensitivity of the topic. At minimum, no service is done by reporting data which have been inadequately analyzed or are based on a sample too small or skewed to reach reliable conclusions. Mistaken reports, even if well intended, may result in unwise public policy, undue public alarm (or undue complacency), and stigma for affected groups. When preliminary data suggest ways of reducing risk, there must be determination of whether the potential benefits of the possibly valid warning are outweighed by the harm which may result from reports which may ultimately be found to be erroneous. In a matter of great moment, there may be an imperative to facilitate research and its dissemination, but such an obligation is not furthered by abandonment of the principles of scientific investigation and communication.¹⁵⁹

Even if normal schedules for publication and release of results are followed, the problem of how to report results remains. Because of the significance that is likely to be attached to new findings about AIDS, researchers bear a special obligation to identify the limitations

155. See generally Am. Ass'n of Univ. Professors, *Regulations Governing Research on Human Subjects: Academic Freedom and the Institutional Review Board*, ACADEME, Dec. 1981, at 358.

156. See, e.g., APA Principles, *supra* note 16, at 633, 637 (Principles 1a, 9, & 9a).

157. The pressure for information about a "hot" topic like AIDS may require researchers to pay particular attention to dissemination of findings to the media in a way that the results will not be distorted. See Schwartz, *AIDS in the Media*, in *SCIENCE IN THE STREETS* (D. Nelkin ed. 1984); Winsten, *Science and the Media: The Boundaries of Truth*, — HEALTH AFFAIRS — (1985); Zich & Temoshok, *A Primer of Pitfalls and Opportunities in AIDS Research*, in *AIDS AND SOCIAL SCIENCE* (D. Feldman ed.) (forthcoming).

158. See *supra* note 67.

159. CPHPR, *supra* note 88, at 26, col. 5.

of the research, to discuss alternative interpretations of findings, and to retain control of the dissemination of the results insofar as possible in order to minimize misleading reports.¹⁶⁰ An example of the risks involved in failure to exercise such caution came when investigators first reported AIDS in children.¹⁶¹ With a boost from a J. A.M.A. editorial, the investigators erroneously concluded that AIDS could be communicated simply through close contact, with the result of creating undue anxiety and increasing pressure to segregate risk groups.¹⁶² Investigators bear a great burden to attempt to ensure that results of research are used in the service of human welfare.¹⁶³

IV. THE ADEQUACY OF LEGAL PROTECTION OF CONFIDENTIALITY

A. Legally Sanctioned Encroachments on Confidentiality

Although there are often competing interests, it is clear from the preceding discussion that forced disclosure of identifiable data in AIDS research may have substantial costs for participants, the researcher, and society. Therefore, it is important to examine carefully ways in which disclosure may be legally compelled. Such scrutiny may allow investigators to foresee and, when possible, prevent unplanned disclosures,¹⁶⁴ and help policy makers identify needs to strengthen legal protection of the confidentiality of data gathered in research on AIDS. Study of potential requirements for involuntary disclosures of data is also necessary so that researchers might accurately inform potential participants as to the limits of confidentiality.

Confidences can be breached by the legal system in several ways. Disclosure of records may be mandated by state reporting laws, agency regulations, or federal statutes. Records may also be subject to disclosure through subpoena by the judicial, legislative, or executive branch of government. Finally, a research participant's confidential records may be voluntarily disclosed by the researcher. The legal system may contribute indirectly to this "voluntary" kind of breach of confidentiality by not providing proper sanctions against such disclosures.

Perhaps the most easily foreseeable form of disclosure is pursuant to state public health laws. Many states have mandated that physicians and hospitals report various diseases to state and local health departments for surveillance purposes.¹⁶⁵ The CDC is the federal

160. See APA Principles, *supra* note 16, at 633, (Principles 1a & 1c).

161. Oleske, Minnefor, Cooper, Thomas, de la Cruz, Ahdich, Guerrero, Joshi & Desposito, *Immune Deficiency in Children*, 249 J. A.M.A. 2345 (1983).

162. *Id.* at 2349. See also Fauci, *The Acquired Immune Deficiency Syndrome: The Ever-Broadening Clinical Spectrum*, 249 J. A.M.A. 2375 (1983).

163. APA Principles, *supra* note 16, at 633, 637 (Preamble & Principle 9).

164. Bayer, *supra* note 141, at 6 (Recommendation 17).

165. See, e.g., CAL. HEALTH & SAFETY CODE §§ 3122-25 (West 1979); FLA. STAT.

agency responsible for coordinating surveillance.¹⁶⁶ The purpose of surveillance is to monitor mortality trends, identify emerging risk groups, document the geographic spread of the disease, and identify areas where preventive efforts may be most useful.¹⁶⁷ CDC has entered into cooperative agreements with many states for AIDS surveillance.¹⁶⁸ More than forty states now have mandatory reporting laws for AIDS.¹⁶⁹ So far, these statutes have required physicians and hospitals to report only diagnosed cases of AIDS. However, given CDC's interest in risk groups, it is conceivable that states could begin to require researchers testing for HTLV-III antibodies to report these findings. Furthermore, any physicians who conduct research on persons with AIDS may be required to report them. Researchers conducting epidemiological studies under contract to CDC may be required to turn over all of their data, including identifying information. Submitting such information to the CDC is a risk to confidentiality because the names and data are being released to a federal public health agency, which may further disseminate the information without participants' informed consent. On at least three occasions, the CDC has released lists of names of AIDS patients to local health agencies not affiliated with the federal government.¹⁷⁰

In one of these instances,¹⁷¹ names were released to the New York Blood Center in connection with a follow-up study on whether AIDS had developed in persons who received the hepatitis B vaccine.¹⁷² This incident was followed by abundant commentary. The CDC was accused of releasing these names by accident,¹⁷³ which caused an understandable uproar in the affected communities. Gay rights groups stated that before AIDS patients can be expected to reveal details of their sexual case histories and admit to illegal acts such as prostitution, the CDC will have to do more than say "trust us" after breaching their confidences in such a manner.¹⁷⁴ The CDC retorted that the re-

§§ 381.605 & 384.06 (1981); NEB. REV. STAT. § 71-503 (1981); N.J. STAT. ANN. §§ 26:4-2 & 26:4-15 (1976); N.Y. PUB. HEALTH LAW § 324(d) (McKinney 1974).

166. H.R. REP. NO. 582, 98th Cong., 1st Sess. (1983).

167. See Novick, *supra* note 115.

168. See Panem, *supra* note 53, at 419.

169. CDC, *supra* note 51, at 248.

170. Marwick, *Confidentiality Issues May Cloud Epidemiologic Studies of AIDS*, 250 J. A.M.A. 1945 (1983).

171. In another instance, names were released to the Los Angeles health department in connection with a "cluster study" in which investigators established that a number of AIDS cases had occurred in individuals following sexual contacts with other person with AIDS. In the final instance, names were released to the New York City, Los Angeles, and San Francisco health departments to eliminate possible duplication of reporting on patients who sought care in several different cities. Marwick, *supra* note 170, at 1945.

172. *Id.* at 1945.

173. Budiansky, *Confidential Matters*, 304 NATURE 478, 478 (1983).

174. *Id.*

lease was not an accident. The names were delivered by hand to a specific physician, who was responsible for determining whether the hepatitis B vaccine was safe. The CDC also asserted that the release was consistent with the requirements of the Privacy Act.¹⁷⁵ News of the incident, rightly or wrongly, intensified distrust of CDC within the gay community, and Congressional investigators questioned whether CDC should have that type of identifying information in the first place.¹⁷⁶ Following this incident, several local health departments adopted the policy of refusing to provide patients' names to the CDC.¹⁷⁷ Their reports to CDC include only number codes that can be linked to the person's name, which the state and local health departments retain. CDC has now adopted a uniform computerized means of encoding names to attempt to ensure that identifying information could not be deliberately or inadvertently released.¹⁷⁸

The question of the proper access to CDC data is illustrative of a more general problem of possible breach of confidentiality through "routine uses" of data or contractual agreements with funding agencies.¹⁷⁹ These types of disclosures are rarely forbidden by the legal system and are not uniformly regulated by internal procedures. An official of an agency funding or directly conducting research may have almost unhindered access to confidential data for program audit, secondary analysis, or routine use. For these purposes, the definition of the "agency" may extend beyond government employees to private contractors hired to analyze the data further or conduct an audit. Fortunately, most of these uses do not require confidential identifying data, although privacy-related problems may emerge because of accidental deductive disclosure, and direct planned disclosure where identifiers are thought to be required.¹⁸⁰

Researchers conducting publicly funded research may minimize the possibility of unnecessarily broad access to raw data by seeking to have any audits or secondary analyses conducted on the research site, preferably by a private contractor. Such a strategy also reduces the possibility of public access to the data under the Freedom of Informa-

175. Privacy Act of 1974, Pub. L. 93-579, 88 Stat. 1896, *codified* at 5 U.S.C. § 552a (1982).

176. Budiansky, *supra* note 173, at 478.

177. *Id.* at 478.

178. This system is called Soundex because the numbered code corresponds to the sound of the name it is used to replace. While Soundex helps to prevent the inadvertent disclosure of identifying information, the code may be broken and the names deciphered. C. Collins, AIDS Legal Guide 22 (n.d.; printed by the Lambda Legal Defense and Education Fund, Inc.).

179. See Privacy Act of 1974, 5 U.S.C. § 552a(a)7 (1982) (defined routine use as "the use of . . . [a] record for a purpose which is compatible with the purpose for which it was collected").

180. See Bayer, *supra* note 141, at 2-3.

tion Act (FOIA).¹⁸¹ Federally supported researchers are confronted with many FOIA requests for research protocols and data from ongoing research projects. For example, requests to the National Institutes of Health (NIH) increased from 300 in 1975 to 1,638 in 1979.¹⁸² Fortunately, this Act does not apply to matters that are specifically exempted from disclosure by statute. The Privacy Act,¹⁸³ which will be discussed later, places some limits on disclosures of identifying information under FOIA. However, the most effective strategy is to prevent creation of an "agency record," so that the raw data are clearly outside the reach of FOIA.¹⁸⁴ It is only when the data come under "government control" that an agency record is created for purposes of the FOIA.¹⁸⁵ Thus, insofar as reports to granting agencies can be limited to summaries and analyses of data, and audits can be performed on site by private contractors, researchers can avoid unintended disclosure of confidential information to a myriad of government workers through routine uses and the public pursuant to the FOIA.¹⁸⁶ Such a strategy also prevents use of the research data as a registry for public health enforcement purposes.¹⁸⁷

Perhaps the most serious threat to confidential material is presented by the subpoena power. Subpoenas may be issued by the judiciary for use in a pending civil or criminal case, or by the legislature or administrative agencies for investigatory purposes. Subpoenas of confidential information about research participants are surprisingly common. Between 1966 and 1976, at least fifty scholars were served subpoenas in eighteen different cases, ordering them to reveal the identities of sources and participants of research. Another thirty scientists were threatened with subpoenas.¹⁸⁸ In a national survey of researchers, about eight percent reported problems of preventing disclosure of confidential information to government authorities.¹⁸⁹

The subpoena power represents a particularly pernicious threat to participants' confidentiality for three reasons. First, subpoenas may be issued for reasons that are unforeseeable and have little to do with the purpose of the research.¹⁹⁰ Therefore, it is often difficult to provide much usable information to potential participants about risks to

181. Freedom of Information Act, 5 U.S.C. § 552 (1982).

182. D. NELKIN, *supra* note 11, at 38.

183. Privacy Act of 1974, 5 U.S.C. § 552a (1982).

184. See generally Morris, Sales & Berman, *Research and the Freedom of Information Act*, 36 AM. PSYCHOLOGIST 819 (1981).

185. *Forsham v. Harris*, 45 U.S. 169 (1980).

186. Morris, Sales & Berman, *supra* note 184, at 826.

187. See Boruch, *supra* note 136.

188. D. NELKIN, *supra* note 11, at 51.

189. *Id.* at 51-52.

190. See, e.g., *In re Grand Jury Subpoena*, 750 F.2d 223 (2d Cir. 1984) (subpoena of records of sociology graduate student studying "The Sociology of the American Restaurant"; fire of suspicious origin occurred in restaurant under study).

confidentiality pursuant to subpoena. Second, when, as is the case with most AIDS research, many participants may have engaged in illegal conduct, information gathered in the course of research may be misused as prosecutorial leads. It is not difficult to imagine an enterprising prosecutor issuing a subpoena for the raw data in a study on AIDS in order to assist the grand jury in investigation of illegal drug use or sexual conduct.¹⁹¹ Besides the deception involved,¹⁹² which is an unethical affront to the dignity of participants,¹⁹³ such misuses of research data are likely to chill any research on AIDS.¹⁹⁴ Third, because subpoenaed material may enter the public domain through admission in litigation or a legislative or administrative hearing, there is a risk of wide dissemination of confidential information and, therefore, especially great risk of embarrassment and other adverse consequences for participants.

Finally, research participants' confidentiality may be threatened by a researcher's voluntarily disclosing such information to others without the participants' consent. The legal system contributes to this type of disclosure by having few, if any, sanctions against such breaches. Persons who have their medical records used for research purposes without their consent, are particularly at risk from this type of disclosure.¹⁹⁵ However, professional self-regulation pursuant to voluntary codes of ethics may provide protection against leaks of confidential information by researchers who have not been legally compelled to disclose the data.¹⁹⁶

B. Legal Means of Protecting Confidentiality

1. *Statutory Protection of Confidentiality*

The legal system can protect confidential data in several ways.¹⁹⁷

191. Cf. Kershaw & Small, *Data Confidentiality and Privacy: Lessons from the New Jersey Negative Income Tax Experiment*, 20 PUB. POL. 281 (1972) (account of prosecutor's subpoena of records of participants in order to discover cheating on welfare assistance).

192. The use of the information is for a purpose other than that to which participants consented.

193. When research is government-sponsored and data are used for the purpose of self-incrimination, there is arguably a violation of the fifth amendment, as well as a breach of the agreement between the investigator and the participant.

194. Because of fear of misuse of data, some gay organizations have already recommended against participation in research. OTA, *supra* note 61, at 48.

195. See *infra* notes 294-97 and accompanying text.

196. Professional self-regulation may be regarded by some as a case of the wolves guarding the henhouse. However, the consequences of disciplinary action by a professional organization may be grave, especially given the interplay between action by professional ethics committees and licensing boards. P. KEITH-SPIEGEL & G. KOOCHEH, *ETHICS IN PSYCHOLOGY: PROFESSIONAL STANDARDS AND CASES* 49 (1985).

197. The discussion hereinafter will focus largely on the federal statutes pertinent to

Statutes can be designed to give all or certain researcher-subject interactions complete or partial immunity to subpoenas and other forms of compelled disclosure. Certificates of confidentiality can be issued for a particular research project so that all confidential material of that study is completely protected from forced disclosure. The court can use a balancing test to determine whether particular data should be recognized as privileged or if it would be overly burdensome to require disclosure. Finally, granting agencies may place limitations on researchers' voluntary disclosures.

A statute providing for absolute protection of confidential research material would provide for all such material to be protected from every possible compelled and voluntary disclosure. Such a statute would, however, probably be overinclusive and result in data availability being severely curtailed even for the purpose of research which minimally intrudes upon privacy.¹⁹⁸ As we have already noted, countervailing interests in protection of public health may justify limited compelled production and release of information to appropriate authorities. Nonetheless, participants' interest in privacy and the interests of the public, the researcher, and participants in the expansion of knowledge about AIDS are likely to be frustrated in the absence of substantial protection of confidentiality of data. The clearest protection would be afforded by a statute barring disclosure under at least some circumstances. Several current federal statutes may offer some protection for AIDS research: the Privacy Act, the Public Health Service Act, the Controlled Substances Act, and the Drug Abuse Office and Treatment Act.

The Privacy Act¹⁹⁹ strongly limits the FOIA by protecting information from being disclosed to the public. However, it does not offer sufficient protection to research data. The Act applies to a narrow range of situations and has eleven exceptions to disclosure restrictions.²⁰⁰ The Act regulates all record systems maintained by federal

social research. For reviews of state laws that protect research see Madden & Lessen, Privacy and Confidentiality of Social Research Information, in PROCEEDINGS OF THE CONFERENCE ON SOLUTIONS TO ETHICAL AND LEGAL PROBLEMS IN SOCIAL RESEARCH (R. Boruch, J. Cecil & J. Ross eds. 1978); C. Knerr, Confidentiality and Behavioral Research: What to do Before the Subpoena Arrives (1978) (paper presented at the Workshop on Research Ethics, Eastern Psychological Ass'n Conference).

198. For needed statutory reforms and proposed model statutes, see Boness & Corder, *The Researcher-Subject Relationship: The Need for Protection and a Model Statute*, 62 GEO. L.J. 243 (1973); Nejelski & Peyser, *A Proposed Researcher's Shield Statute: Text and Summary of Commentary*, in SOCIAL RESEARCH IN CONFLICT WITH LAW AND ETHICS (P. Nejelski ed. 1976) [hereinafter cited as RESEARCH IN CONFLICT].

199. Privacy Act of 1974, 5 U.S.C. § 552a (1982).

200. The conditions for disclosure are set forth at § 552(b) of the Privacy Act:

No agency shall disclose any record which is contained in a system of

agencies, including research and statistical record systems. Private record systems or those maintained by state or local governments without federal assistance are, however, exempt from the Act. Furthermore, even research record systems that are federally funded but not directly maintained by the funding agency are beyond protection of the Act. Only if a federal agency subcontracts for a record system that it otherwise would have established and maintained is the record system regulated by the Act. Records that are not individually identifiable are not regulated by the Act. Moreover, the apparent coverage of individually identifiable data is deceptive because what is individually identifiable is not always clear. Materials that do not contain names, social security numbers, or other obvious identifiers may still contain information that renders individuals' identity discoverable by inference or deduction. Thus, about the only protection the Privacy Act does offer is against public solicitations for information that is obviously individually identifiable, and is maintained by the federal government.

The Drug Abuse Office and Treatment Act of 1972²⁰¹ is another statute that may offer limited protection to AIDS research. However, this statute applies only to drug abuse prevention functions.²⁰² Therefore, few, if any, AIDS research projects would be covered by this statute. Research on IV drug users might fall under the protection of this statute, but it would have to be shown that the research somehow applied to drug abuse *prevention*. Disclosure under the Drug Abuse Act

records by any means of communication to any person, or to another agency, except pursuant to a written request by, or with the prior written consent, of the individual to whom the record pertains, unless disclosure of the record would be [the following are those exceptions pertinent to research]:

(1) to those officers and employees of the agency which maintains the record who have a need for the record in the performance of their duties; . . . (5) a recipient who has provided the agency with advance adequate written assurance that the record will be used solely as a statistical research or reporting record, and the record is to be transferred in a form that is not individually identifiable; . . . (7) to another agency or to an instrumentality of any governmental jurisdiction within or under the control of the United States for a civil or criminal law enforcement activity if the activity is authorized by law, and if the head of the agency or instrumentality has made a written request to the agency which maintains the record specifying the particular portion desired and the law enforcement activity for which the record is sought; (8) to a person pursuant to a showing of compelling circumstances affecting the health or safety of an individual if upon such disclosure notification is transmitted to the last known address of such individual; (9) to either House or Congress, or, to the extent of matter within its jurisdiction, any committee or subcommittee thereof, any joint committee of Congress or subcommittee of any such committee; . . . (11) pursuant to the order of a court of competent jurisdiction.

201. 21 U.S.C. § 1175(a) (1982).

202. *Id.*

is more limited than under the Privacy Act alone, but the threat of subpoena is still present.²⁰³

Studies that are covered by the Drug Abuse Act may also be covered by the Controlled Substances Act,²⁰⁴ which introduces the availability of certificates of confidentiality. Certificates of confidentiality offer one of the best protections of confidentiality because they guard against all compelled disclosures. However, the protection offered by these certificates is not automatic; rather, it requires a grant of confidentiality.²⁰⁵ Moreover, changes in the implementing regulation of the Controlled Substances Act have, unfortunately, restricted this protection to a narrow range of law enforcement studies.²⁰⁶ Therefore, it is unlikely that any AIDS research would be eligible for a grant of confidentiality under this statute today. Prior to these changes, protection under the Act was available to a broad range of social research studies investigating issues of drug abuse.²⁰⁷

The Public Health Service Act,²⁰⁸ which also provides for certificates of confidentiality, is more likely to provide protection to psychosocial research on AIDS. The Public Health Service Act is the statute most frequently cited as providing protection for private social science research. The Act permits the Secretary of HHS to:

[A]uthorize 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,

203. The statute states:

Records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any drug abuse prevention conducted, regulated, or directly or indirectly assisted by any department or agency of the United States shall . . . be confidential and be disclosed only for the purposes and under the circumstances expressly authorized

21 U.S.C. § 1175(a) (1982).

The "drug abuse prevention" function is defined to apply to research as well as drug-related education, training, treatment, and rehabilitation. 42 C.F.R. § 2.1 (1984). The circumstances under which records can be disclosed include: (a) to medical personnel when a medical emergency exists; (b) to qualified personnel for scientific research, management audits, financial audits, or program evaluation, as long as the patients' identities are not disclosed in any way; (c) if authorized by an appropriate court order. No provision is made for the patient to receive notice or be heard if a court is requested to authorize a subpoena. 21 U.S.C. § 1175(b) (1982).

204. 21 U.S.C. §§ 801 to 904 (1982).

205. *Id.* at § 872(c). See Reatig, *Confidentiality Certificates: A Measure of Privacy Protection*, 1(3) IRB 1 (1979).

206. 21 U.S.C. § 872(a)(2)-(6) (1982); 21 C.F.R. § 1316.21 (1984).

207. R. BORUCH & J. CECIL, *ASSURING THE CONFIDENTIALITY OF SOCIAL RESEARCH DATA* 252 (1979).

208. 42 U.S.C. § 242a (1982).

state, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals.²⁰⁹

A major limitation of the Public Health Service Act is that protection extends only to names, other identifying characteristics of participants, or "any other item or combination of data about a research subject which could reasonably lead directly or indirectly by reference to other information to identification of the research subject."²¹⁰ The research data per se are not protected. Therefore, a subpoena for the release of all research information pertaining to a known participant may be enforceable.²¹¹ However, this question has not yet been confronted by the courts.

"Mental health research" is not defined in the Public Health Service Act, but research is defined broadly as any "systematic study directed toward new or fuller knowledge of the subject studied."²¹² Therefore most psychosocial research on AIDS should be eligible for protection under this statute because it is obviously intended to produce knowledge, which may be construed as relevant to the mental health of AIDS patients or risk groups. Again, however, one of the limitations of this type of statute is that its application is discretionary. Researchers must apply to, and convince, the Secretary of HHS to issue a grant of confidentiality in order to protect their research data.²¹³ Our experience is that few investigators are even aware of the possibility of acquiring certificates of confidentiality, and fewer still go to the trouble of applying for them.²¹⁴ However, it also appears that the existence of certificates has made some studies possible that would not otherwise have been undertaken.²¹⁵ It seems likely that adequate dissemination of information to prospective researchers about the nature of certificates of confidentiality and the procedures for obtaining them would help to stimulate research on sensitive topics related to mental health and substance abuse, including AIDS.

2. *Judicial Protection of Confidentiality*

Statutory protection of the confidentiality of research data is preferable, not only because it provides a clear statement of policy, but

209. *Id.* at § 242a.

210. 42 C.F.R. § 2a(2)(g) (1984).

211. Boruch, *Methods for Resolving Privacy Problems in Social Research*, in *ETHICAL ISSUES IN SOCIAL SCIENCE RESEARCH* (T. Beauchamp, R. Faden, R. Wallace & L. Walters eds. 1982).

212. 42 C.F.R. § 2a(2)(c) (1984).

213. *Id.* at § 242a(a).

214. See also Nelson & Hedrick, *The Statutory Protection of Confidential Research Data: Synthesis and Evaluation*, in *SOLUTIONS TO ETHICAL AND LEGAL PROBLEMS IN SOCIAL RESEARCH* 213, 223 (R. Boruch & J. Cecil eds. 1983) [hereinafter cited as *SOLUTIONS*].

215. See *id.* at 226-29.

also because it provides information *before* there is an attempt to breach confidentiality about its limits. After a subpoena is ordered for the production of research materials, the researcher may move that it be quashed,²¹⁶ and the court then must decide whether or not to order compliance with the subpoena. Obviously, it is risky to rely on a court's case-by-case judgments in protecting confidentiality.

In deciding whether to enforce a subpoena, the court must examine and weigh many factors pursuant to prevailing procedural rules. The rules of civil and criminal procedure are very similar in their provisions governing discovery. The Federal Rules of Civil Procedure provide that "parties may obtain discovery regarding any matter, *not privileged*, which is relevant to the subject matter involved in the pending action"²¹⁷ The Federal Rules of Evidence maintain that for privileges to be recognized they must be constitutionally derived, statutorily created, recognized at common law, or, for civil proceedings, prevailing in state law.²¹⁸ If no privilege is found to exist, there is an additional argument that can be made to protect confidentiality of data. Rule 45(b) of the Federal Rules of Civil Procedure, and Rule 17(c) of the Rules of Criminal Procedure, provide that a subpoena can be used to force production of documentary evidence, but a court may quash or modify the subpoena if it is unreasonable and ("or" for criminal) oppressive.²¹⁹ Of particular importance for psychosocial research on AIDS, discovery also may be limited if justice so demands in order to protect someone from embarrassment.²²⁰

Courts normally employ a three-step analysis to determine whether a subpoena is unreasonable and oppressive.²²¹ First, the court must determine that the requested information is relevant to the case at hand. Information is relevant if it is "reasonably calculated to lead to the discovery of admissible evidence."²²² If the researcher can convince the court that the subpoenaed information is not relevant to the legal proceeding at hand, the information would not have to be disclosed. Once the court has established that the subpoenaed information is relevant, the court must analyze the requesting party's need for the information. To ascertain need, the court must determine the importance of the information to the requesting party, including the likelihood that the requesting party could get the

216. Such action is arguably ethically required. APA Principles, *supra* note 16, at 634 (Principle 3d); Bayer, *supra* note 141, at 4 (Recommendation 10); CPHPR, *supra* note 88, at 26, col. 4.

217. FED. R. CIV. P. 26(b)(1).

218. FED. R. EVID. 501.

219. FED. R. CIV. P. 45(b); FED. R. CRIM. P. 17(c).

220. FED. R. CIV. P. 26(c).

221. Comment, *Forced Disclosure of Academic Research*, 37 VAND. L. REV. 585, 596 (1984).

222. FED. R. CIV. P. 26(b)(1).

information from another source. Once the court has determined that the subpoenaed material is relevant and the requesting party needs the information, the court must consider the burden that enforcement of the subpoena would impose. The burden of showing the unreasonable and oppressive nature of the subpoena is upon the subpoenaed person. Because no single factor is conclusive evidence of unreasonableness, courts must weigh all the factors on a case by case basis.²²³

No absolute privilege has been recognized for researcher-participant interactions, although many commentators have argued that there should be one.²²⁴ Some of the arguments for an absolute privilege will be presented briefly, since many of these points may be considered in determining unreasonableness, or a privilege recognized on a case by case basis.

If researcher-participant communications were within the protection of the Constitution, research information would always be withheld regardless of its importance to the litigation. The most plausible constitutional argument for an absolute researcher privilege rests on the first amendment. Academic freedom and communications necessary for research are arguably protected by the first amendment guarantees of freedom of the press and freedom of speech. In *United States v. Doe*,²²⁵ perhaps the best known attempt to apply this argument, Samuel Popkin, a political scientist, claimed immunity from inquiries by a grand jury into his knowledge of the leaks of the Pentagon Papers. Noting that a promise of confidentiality is sometimes necessary in order to conduct research involving human participants, Popkin reasoned that enforcement of the subpoena would deter other persons from disclosing private information to researchers, thereby restricting the free flow of information protected by the first amendment.²²⁶ Neither the First Circuit Court of Appeals in *Doe*, nor any other court, has been persuaded that the flow of information to the public would be constricted in the absence of an absolute research privilege.²²⁷ However, the Seventh Circuit has recognized a first amendment right to academic freedom, such that a subpoena of data

223. Comment, *Free Press, Privacy and Privilege: Protection of Researcher-Subject Communications*, 17 GEO. L. REV. 1009, 1010 (1983).

224. See *supra* note 198.

225. 460 F.2d 328 (1st Cir. 1972).

226. U.S. CONST. amend. I states: "Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble, and to petition the Government for a redress of grievances."

227. See, e.g., *In re Grand Jury Subpoena Dated Jan. 4, 1984*, 750 F.2d 223 (2d Cir. 1984). The court found no privilege without:

a threshold showing consisting of a detailed description of the nature and seriousness of the scholarly study in question, of the methodology employed, of the need for assurances of confidentiality to various sources to

collected by a university-based scholar would be constitutionally tolerable only when a compelling need for the information could be demonstrated.²²⁸ This argument is likely to be most persuasive when research is ongoing (i.e., the results of the study have not yet been published), so that a subpoena of data recordings poses a special threat of intrusion into the academic enterprise.²²⁹

A similar qualification limits reliance on the due process clause of the fourteenth amendment.²³⁰ Under this argument, it is claimed that forced disclosure of data deprives a researcher of property without due process.²³¹ Before publication, the researcher may be relying on the research to attain enhanced standing in the academic community. The value of the research to the investigator would be greatly diminished if results were disclosed prematurely and scholarly publication were therefore foreclosed. The researcher forfeits her property interest once the results are published, because she has voluntarily released the research to the community.

Another argument under the fourteenth amendment is that a researcher's interest in personal liberty is violated by forced disclosure of data. The argument rests on the assumption that a "researcher has a personal right to conduct his research free from unjustifiable interruption."²³² No court has yet addressed this issue in the context of forced disclosure of research.

A final constitutional argument for the recognition of a privilege rests on the participants' rather than the researcher's rights. There is general agreement that "[p]ublic disclosure of highly sensitive or intimate information given to the researcher in confidence can damage the privacy interests of the subject."²³³ Perhaps because it is the re-

conduct the study, and of the fact that the disclosure requested by the subpoena will seriously impinge upon that confidentiality.

Id. at 225. See also *Buchanan v. American Motors Corp.*, 697 F.2d 151 (6th Cir. 1983) (subpoena requiring expert to spend many days collating raw data was unduly burdensome; court assumed without deciding that no absolute researcher privilege existed); *Wright v. Jeep Corp.*, 547 F. Supp. 871 (E.D. Mich. 1982) (researcher compelled to testify); *Andrews v. Eli Lilly & Co.*, 97 F.R.D. 494 (N.D. Ill. 1983) (manufacturer's need for evidence insufficient to justify possible chilling of research on DES); *Lampshire v. Procter & Gamble Co.*, 94 F.R.D. 58 (N.D. Ga. 1982) (manufacturer's need for evidence insufficient to justify intrusion upon participants' privacy). See also *Branzburg v. Hayes*, 408 U.S. 665 (1972) (limited journalist privilege).

228. *Dow Chem. Co. v. Allen*, 672 F.2d 1262 (7th Cir. 1982).

229. A subpoena of data in an ongoing study risks the necessity of changing the design and, in effect, changing the nature of the academic inquiry. This risk is especially great when the scope of the subpoena includes *future* recordings of data.

230. U.S. CONST. amend. XIV, § 1: "No state shall . . . deprive any person of life, liberty, or property, without due process of law . . ."

231. Comment, *supra* note 221, at 609-10.

232. *Id.* at 610.

233. Comment, *supra* note 223, at 1013.

searcher who is in a position to contest a subpoena of research data, this argument also has yet to be addressed by the courts. Indeed, a hallmark of decisions on the enforcement of subpoenas of research data has been a lack of attention to participants' interests.²³⁴ When the sensitivity of research protocols has been considered, courts have tended not to be concerned with participants' privacy per se. Rather, courts have tried to avoid deterring participants' willingness to become involved in sensitive research and, therefore, infringing the public's and the researcher's interests in the pursuit of knowledge.²³⁵

The constitutional arguments, in themselves, have been insufficient for recognition of a researcher-participant privilege. A more viable approach may be to rely upon the common law privilege, as codified in the Federal Rules of Evidence.²³⁶ The Supreme Court has held that, by enacting Rule 501, Congress "manifested an affirmative intention not to freeze the law of privilege."²³⁷ Courts are free, therefore, to develop rules of privilege on a case by case basis. In so doing, the practice has been to rely on Dean Wigmore's four-pronged test: (1) the communication must have originated in a confidential relationship; (2) the preservation of confidentiality must be necessary for the full and satisfactory maintenance of the relationship; (3) the relationship must be one that is important to the community; and (4) the injury to the relationship that would accrue from breach of confidentiality must be greater than the benefit that would be gained for the correct disposal of the litigation.²³⁸

Although courts have been reluctant to recognize a broad researcher-participant privilege,²³⁹ psychosocial research on AIDS is apt generally to meet the Wigmore test. The first three prongs seem clearly applicable. Participants are generally promised confidentiality, and that pledge is probably necessary for recruitment of partici-

234. The only reported case in which a subpoena has been quashed on the basis of participants' privacy is *Lampshire v. Procter & Gamble*, 94 F.R.D. 58 (N.D. Ga. 1982). In a civil action for injuries resulting from toxic shock syndrome, purportedly incurred from the use of tampons, Procter & Gamble subpoenaed the records of the CDC. These records included "information about medical history, personal hygiene, menstrual flow, sexual activity, contraceptive methods, history of pregnancies, douching habits, and tampon use." *Id.* at 60 n.2. *Lampshire* was decided on the basis of the procedural balancing test, FED. R. CIV. P. (26)(c), not the constitutional right to privacy.

235. See, e.g., *Andrews v. Eli Lilly & Co.*, 97 F.R.D. 494 (N.D. Ill. 1983) (records of researcher about links between mothers' prenatal ingestion of DES and vaginal cancer in daughters); *Richards of Rockford, Inc., v. Pacific Gas & Elec. Co.*, 71 F.R.D. 388 (N.D. Cal. 1976) (records of confidential interviews with employees about utility's decision making about environmental issues).

236. FED. R. EVID. 501.

237. *Trammel v. United States*, 445 U.S. 40, 47 (1980).

238. 8 J. WIGMORE, EVIDENCE IN TRIALS AT COMMON LAW § 2285 (3d ed. 1961).

239. See *supra* note 227.

pants and receipt of candid responses. The importance of research on AIDS to the public health is also clear. With respect to the first three prongs, the only possible problem would be that the full explication of the limits of confidentiality in obtaining informed consent to participate in the study may serve ironically to diminish subjective expectations of privacy. However, in view of the sensitive nature of psychosocial research on AIDS and the potential harms that may result from disclosure of records in such research, participants still may reasonably expect maintenance of privacy.²⁴⁰

The fourth prong in the Wigmore test may be more problematic, simply because it is more unpredictable. The balancing test involved is necessarily case-specific and dependent upon trial judge discretion. Although it is difficult to imagine many scenarios in which the balance would not tip toward protection of confidentiality, the range of potential needs for the research data as evidence is sufficiently great to limit one's ability to confidently predict the reliability of Rule 501 in creating a common law privilege.

3. *Administrative Protection of Confidentiality*

So far we have discussed ways in which the legal system may compel breaches of confidentiality and limitations on this authority. The legal system also may exercise control over *researchers'* abuse of the privacy of participants in their studies. This regulation of researchers' behavior is primarily through administrative mechanisms.

Notably, proposals for research on AIDS almost invariably involve more than minimal risk to participants,²⁴¹ and should be accorded full IRB review before implementation.²⁴² IRBs will in turn probably find it useful to consult with affected groups.²⁴³ When federal funding is requested, peer reviewers and agency officers for protection of human participants provide additional scrutiny of the ethics of the research. This high level of review should help to ensure that protections of confidentiality are built into the research design whenever possible,²⁴⁴ and that privacy is not vulnerable simply because of investigator carelessness or ignorance.

Review of the adequacy of protections built into a research design

240. Cf. Melton, *supra* note 106, at 478-80, 486 (applicability of fourth amendment should not be dependent upon subjective expectation of privacy, although instances in which such expectations are present may establish a minimum zone of privacy).

241. Bayer, *supra* note 141, at 5 (Recommendation 15).

242. *Id.*

243. OPRR, *supra* note 87, at 2; Bayer, *supra* note 141, at 7 (Recommendation 23); CPHPR, *supra* note 88, at 26, col. 2.

244. OPRR, *supra* note 87, at 3-4; Bayer, *supra* note 141, at 7 (Recommendation 17); CPHPR, *supra* note 88, at 26, col. 4. For a review of methodological and legal strategies to protect confidentiality, see generally SOLUTIONS, *supra* note 214.

does not guarantee, however, that researchers will in fact exercise proper stewardship of the data. Nonetheless, the availability of administrative remedies for unethical conduct may serve as an efficient, effective deterrent. Agencies can tailor grant restrictions to the particular ethical issues raised by a project (e.g., the need to protect confidentiality in research on AIDS), and they can put teeth into these restrictions through their effects on investigators' livelihood. Administrative sanctions may include: (1) termination of the grant; (2) mandatory refund of the grant; (3) suspension of pending future grants; (4) the attachment of the record of the incident to any application for future grants; and (5) termination of eligibility for grant awards.²⁴⁵ Researchers may remain liable for civil²⁴⁶ or criminal²⁴⁷

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245. Greenstein, *Federal Contractors and Grantees: What Are Your First Amendment Rights?*, 24 JURIMETRICS J. 197 (1984). There is a strong argument that all necessary restrictions on research should be imposed through the grant or contract. In this way, the terms for disclosure can be tailored to fit the particular case. Consequently, what is covered should be unambiguous, and what is permitted or prohibited should be clear to both the researcher and the government. Furthermore, the researcher should be more informed about disclosure requirements because the researcher is more likely to read her grant or contract than the Code of Federal Regulations. However, it is questionable whether such restrictions would be legally binding on courts, and individual grant restrictions lack uniformity. Furthermore, granting agencies do not presently enforce possible sanctions for inappropriate voluntary disclosure.
246. Three possible civil bases exist for a subject to sue a researcher for disclosure of her confidential data, whether the disclosure was made voluntarily or under court order by the researcher. First, the respondent may seek a tort recovery based on breach by the investigator of a duty not to invade her privacy by disclosing confidential information. Teitelbaum, *Spurious, Tractable and Intractable Legal Problems: A Positivist Approach to Law and Social Science Research*, in SOLUTIONS, *supra* note 214, at 11, 27-29. However, if disclosure was made pursuant to judicial or legislative proceedings, the disclosure is considered privileged and is not subject to legal redress. Second, the participant might claim that a contract between the participant and the researcher existed and included a promise of confidentiality that was breached. *Id.* at 29-32. Third, a participant may claim that the researcher acquired the sensitive information by a misrepresentation about its confidentiality. *Id.* at 32-36.
247. It has been suggested that "having obtained information about criminal offenses from specific, known and identified subjects of a research project, the researchers stand in a posture a [sic] harboring information." Wolfgang, *Ethical Issues of Research in Criminology*, in RESEARCH IN CONFLICT, *supra* note 198, at 25, 29. Three possible theories of liability have been proposed: (1) researchers who keep secret evidence of crimes committed by others are accessories after the fact to those crimes; (2) they are guilty of the separate crime of misprision of felony; (3) they are guilty of the crime of obstruction of justice. *Id.* at 29-30. However, researchers probably do not need to worry about these possibilities. The first does not apply to researchers, because the most common rule is that mere failure to give information of a crime will not, in the absence of other acts of comfort or assistance, make one an accessory after the fact. *Levering v. Commonwealth*, 132 Ky. 666, 117 S.W. 253 (1909). The second possibility is unlikely because misprision of felony has been abandoned or unrecognized in most jurisdictions. Teitelbaum, *supra* note 246, at 18. The final consideration does not reach silence alone. The

sanctions, but administrative sanctions resulting from carefully constructed grant restrictions are probably more likely to apply.²⁴⁸

V. THE NEED FOR LEGAL REFORM

The need for psychosocial research on AIDS is clear. So are the ethical and pragmatic difficulties in conducting such research, absent guarantees of confidentiality. Keeping such policy considerations in mind, it is useful to summarize our discussion of legal protection of, and threats to, the privacy of participants in AIDS research.

Reporting requirements pursuant to the state's authority to protect the public health represent the form of compelled disclosure that is most obviously and particularly relevant to research on AIDS. In their present form, however, these requirements may actually provide little threat to research on AIDS. Presumably, identified AIDS patients already will have been reported, and cases diagnosed in the process of conducting research (perhaps unlikely in psychosocial research) eventually would be reported in any event. Therefore, insofar as reporting requirements are limited to identification of AIDS patients, they are likely to create little additional threat to privacy, although there is the possibility that requirements would be initiated for disclosure of research data more generally (as part of the state's surveillance of AIDS cases), or reporting of seropositivity to HTLV-III antibodies. In such an instance, the public's need for information about the illness must be carefully balanced against the intrusion upon participants' privacy, and the compulsory disclosure and diffusion of personal information should be no greater than necessary to meet the state's compelling interest in preventing the spread of AIDS and developing an effective treatment for it. Even in such a circumstance, collection and storage of the data perhaps should be the responsibility of a private agency, so as to minimize the public's access to personal information under the FOIA, and public health agencies' confusion of their research and police functions.²⁴⁹

Assuming that *some* intrusion upon the privacy of AIDS patients and risk groups is justifiable, the most serious risks to participants appear to emanate from the possibility of unnecessarily broad distribution of data under the guise of "routine uses," and the threat of

essence of obstruction of justice lies in the commission of acts that impede, rather than in failure to aid, the administration of justice. *Id.* at 20-22. It is noteworthy that these theories of potential criminal liability of researchers apply to attempts to protect participants; there are unlikely to be plausible arguments for criminal liability for researchers who breach confidentiality.

248. Teitelbaum's review, *supra* note 246, makes clear that potential civil liability is "tractable." Administrative remedies can be efficiently applied and based on rules that are clearly tailored to the area of study. *See supra* note 245.

249. *See* Boruch, *supra* note 136; Novick, *supra* note 115.

subpoena. There are few legal constraints on granting agencies, public health agencies, and researchers themselves in how widely personal information about participants is diffused. Perhaps IRB review and the ethical norms of the relevant professions will act as adequate constraints on "voluntary" disclosure of personal information by agency personnel or researchers themselves. However, even assuming that such moral scruples are widespread, clear administrative guidelines are needed within the relevant granting and research agencies governing access of agency staff, external researchers, and public health officials to data gathered in studies on AIDS.

Confidentiality certificates under the Public Health Service Act appear to offer the best advance protection currently available against subpoenas. Researchers on psychosocial aspects of AIDS should routinely seek such grants of confidentiality. Nevertheless, as a matter of public policy, the current program of certificates of confidentiality is inadequate. The protection of participants should not be dependent upon whether the researcher studying them has sufficient knowledge of the Public Health Service Act and is sufficiently diligent to apply for a certificate. Moreover, the uncertainty of the scope of the certificates (e.g., whether they protect the data of an individual known by the party issuing the subpoena to have participated) places researchers in a position in which they cannot truthfully guarantee potential participants that their communications will be immune from subpoena.

If a subpoena is issued, the researcher is obligated ethically to attempt to have it quashed.²⁵⁰ Even without a certificate of confidentiality, there are a number of grounds on which to base a motion to quash. The researcher may be able to make a successful argument that she would be unduly burdened, or that academic freedom and her property interest in the data justify immunity from subpoena. These arguments are not likely to be uniformly persuasive, especially if the study has already been published. The most generally applicable bases for a claim of invulnerability of AIDS research to subpoena would appear to be potential embarrassment to the participants greater than the need for the information in the legal proceeding, and a common law case-by-case privilege. Even these arguments are necessarily so case-specific as to provide little reassurance to the researcher who wishes to promise potential participants confidentiality and protect actual participants from harm.

In order to promote psychosocial research on AIDS and to protect participants from undue invasion of privacy and other social, legal, and economic harms, a statute is needed to minimize disclosure of identifi-

250. APA Principles, *supra* note 16, at 634, 635-36 (Principles 3d & 5). Note that Principle 3d gives unclear guidance about the stance psychologists should take if the law (i.e., an enforceable subpoena) and ethics (i.e., the duty to protect confidentiality) remain in conflict.

able personal information without the consent of participants. Action by Congress would be the preferable approach to the gaps in current law,²⁵¹ but the state legislatures may provide some protection of participants in the meantime.²⁵²

In 1983, New York enacted a statute that seems to strike a just balance between societal and individual interests in the conduct of research on AIDS.²⁵³ The New York law provides an absolute privilege against admission of information gathered in AIDS research as evidence in any legal proceedings.²⁵⁴ Whatever the merits of a researcher-participant privilege generally,²⁵⁵ it seems clear to us that the public's interest in promotion of research on AIDS and participants' interest in privacy justify an absolute privilege to protect data gathered from human participants. Even on a case-by-case basis, it is hard to imagine instances in which the litigants' need for information from research data would outweigh the public's and participants' interests. Regardless, in order not to chill necessary research, the AIDS researcher-participant privilege must be a matter of *policy*, and not be dependent upon case-by-case application.

At the same time, a bar on *any* disclosure of information from records of AIDS patients and research participants would unduly hamper research. Again, the New York statute seems to strike a proper balance. It makes research on AIDS generally confidential,²⁵⁶ and it specifically bars publication of data in such a way that the identities of participants can be inferred.²⁵⁷ At the same time, however, the statute permits the commissioner of public health to give researchers access to the department's records of mandatory reports of AIDS cases.²⁵⁸ Insofar as the threat to public health is so great as to require such disclosure, actually requiring reports is a pointless intrusion upon patients' privacy unless the data are in fact used to increase knowledge

251. The major source of regulation of research with human participants is federal, and regulations already exist for other special populations or situations. *See, e.g.*, 45 C.F.R. §§ 46.201 to 211 (1984) (fetuses and pregnant women); 45 C.F.R. §§ 46.301 to 06 (1984) (prisoners); 45 C.F.R. § 46.401.09 (1984) (children). IRBs look to federal regulations for guidance, and a federal approach would maximize consistency of expectations by researchers and investigators. *See* Bayer, *supra* note 141, at 7 (Recommendation 22). Congress's Office of Technology Assessment has indicated the probable need for statutory protection of AIDS research. OTA, *supra* note 61, at 47-48.

252. Unsurprisingly, states with large numbers of AIDS patients have been first to enact legislation promoting and regulating research on the illness. *See, e.g.*, CAL. HEALTH & SAFETY CODE §§ 195-199.5 (West Cum. Supp. 1985); N.Y. PUB. HEALTH LAW §§ 2775-79 (McKinney Cum. Supp. 1984).

253. N.Y. PUB. HEALTH LAW §§ 2775-79 (McKinney Cum. Supp. 1984).

254. *Id.* at § 2776(2), *applying id.* at § 206(j).

255. *See supra* notes 224-40 and accompanying text.

256. N.Y. PUB. HEALTH LAW § 2776(2) (McKinney Cum. Supp. 1984).

257. *Id.*

258. *Id.*

about AIDS.²⁵⁹ Beyond this minimal use of records pursuant to public health authority, disclosure of identifiable research data to others, including other researchers, would presumably require the informed consent of the participants involved.²⁶⁰

The one shortcoming of the New York statute is that it provides no remedies for violation of participants' confidentiality. Administrative sanctions should be available for grantees²⁶¹ and state employees²⁶² who so violate the law. The federal Office for Protection from Research Risks in the Department of Health and Human Services has developed procedures for application of such sanctions that provide for careful investigation of complaints, without undue threats to researchers' reputations in the meantime.²⁶³ In addition, agencies involved in research, or funding for research, on AIDS should develop clear policies as to who may have access to the data, and procedures for insuring that these policies are implemented. IRBs should be charged with making certain that individual researchers have given comparable care to the development of means of protecting human participants in AIDS research, including, under present law, applications for certificates of confidentiality.²⁶⁴

As suggested in Section I of this Article, some of the ethical problems faced in psychosocial research on AIDS are inherent. The basic conflict between societal interests and individual privacy cannot be eradicated by new legislation. The issues involved, especially in regard to protection of confidentiality would, however, be much less acute if adequate legal protections were in place. Until such legislation is enacted, researchers need to give careful attention to the ethical dilemmas at each step in the research,²⁶⁵ and to obtain the advice

259. Unless there is a clear intent actually to *use* the data gathered in surveillance, authorities arguably are exceeding their statutory authority in jurisdictions in which the purpose of reporting is expressly noted in the statute. *See, e.g.,* N.Y. PUB. HEALTH LAW § 206(i)(j) (McKinney 1971) (providing for "such scientific duties and research which have for their purpose the reduction of morbidity and mortality and the improvement of the quality of medical care through the conduction of medical audits"). There is also a plausible argument that mandatory reporting simply for the sake of reporting violates patients' constitutional right to privacy. The production of highly personal information is compelled without any real state interest.

260. The statute does permit access to the records for "the conduction of medical audits." *Id.* at § 206(l)(j). It would be important to have clear agency policy to limit access under this provision.

261. *See supra* notes 245-48 and accompanying text.

262. *See supra* notes 179-80 and accompanying text.

263. Such procedures were developed by OPRR to deal with allegations of scientific fraud. C. McCarthy, Issues of Noncompliance with Human Participants Regulations (paper presented to the Sci. Pol. Forum, Am. Psychological Ass'n, Sept. 21, 1984).

264. *See supra* notes 241-44 and accompanying text.

265. APA Principles, *supra* note 16, at 637-38 (Principle 9), describes the decision

of peers, affected groups, and the general public.²⁶⁶ Because confidentiality cannot be fully guaranteed, researchers should minimize use of identifiers. When identifiers are or may be necessary for the research, participants should be fully informed of the risks and given the option of whether to have their data stored. In view of the potential gravity of the consequences of the decision, special effort should be made to ensure that consent truly is informed, competent, and voluntary.²⁶⁷ In that regard, we have appended guidelines designed to meet ethical and legal requirements for informed consent.

Finally, we should return to the point that we made at the beginning of this Article. Conflicts of interest are pervasive in psychosocial research with human participants. The examination of these conflicts in research on AIDS highlights the issues. Because the conflicts are particularly stark and complex, the consequences of conducting or not conducting research are especially serious, and the general topic is one of great public concern. Nonetheless, the basic dilemmas are not unique to research on AIDS or even other socially sensitive topics. Our look at the ethical and legal context of research on AIDS raises broader questions of the adequacy of protection of human participants in research. Although the development in the past two decades of professional and governmental mechanisms for regulation of human re-

making at each point in the research process. See also CPHPR, *supra* note 88, at 26, col. 2:

[I]t is important to note that consultation — even intensive consultation with peers and affected groups — does not absolve the researcher of ethical responsibility for the study and its conduct, even when all legal requirements for review are met. On the other hand, careful ethical deliberation does not, of course, abrogate the requirement to follow legal procedures for protection of human participants. Especially when there is persistent pressure for answers to the public health issues, researchers need to remain ethically vigilant at all phases of the investigation.

266. See *supra* note 243. Consultation with affected groups serves multiple purposes:

It increases the likelihood that proper attention is given to the various interests relevant to a decision as to whether and how a study is designed, implemented, and reported. It also provides a means of protection of participants from "overresearch" and undue exploitation. Extraordinary review also serves as a check on the methodological integrity of the study, which is important not only for scientific purposes; it is also relevant to the determination of whether the study is sufficiently promising to warrant imposition upon participants and possible threats to their privacy. Research with gay men, for example, is less likely to result in ineffective recruitment of participants, failure to ask the most probative questions, or misinterpretation of data (and accompanying deleterious social consequences), if representatives of gay groups are consulted.

CPHPR *supra* note 88, at 26, col. 2.

267. This effort should include more than writing adequate consent forms. Diligent efforts should be made to ensure that participants perceive themselves as having a choice and that they understand fully the nature and potential consequence of their decision.

search is laudatory, these procedures are insufficient. The law should be reformed to provide better protection of participants' privacy. Legislators, researchers, and the general public need to examine more carefully the conflicts between individual and social good inherent in human research.

APPENDIX
COMPOSITE GUIDELINES FOR INFORMED CONSENT
TO PSYCHOSOCIAL RESEARCH ON AIDS

A. The Elements of Informed Consent

The solicitation of knowing, intelligent, and voluntary consent to research is an important recognition of the autonomy of potential participants and an attempt to "humanize" the relationship between researcher and participant.²⁶⁸ Careful attention to this process is especially important in research on AIDS. Because psychosocial research on AIDS typically subjects participants to some risks, respect for persons demands that they be permitted to make a fully informed choice whether to participate.²⁶⁹ In particular, because confidentiality is very difficult to guarantee in research, and participants may be harmed by disclosure of their data, or even simply the fact of their participation, it is essential that participants be informed as to whom and when data may be disclosed.

There are, of course, countervailing pressures that work against such complete honesty. For instance, if all possible harms were discussed in detail, few people may be willing to participate in such a risky affair. Ethically, this should be a concern only insofar as participants are unduly alarmed or simply confused by a complex list of risks and benefits;²⁷⁰ less than full disclosure defeats the purpose of obtaining consent. If the public's need for the research is so great that it will be conducted despite potential participants' desires not to be involved (assuming that they are fully informed), there should be a straightforward decision to that effect, not a deceitful pro forma exercise in obtaining "informed" consent.

A second countervailing consideration is that if the consent form is

268. See generally J. KATZ, *supra* note 3.

269. See generally Bayer, *supra* note 141; CPHPR, *supra* note 88; OPRR, *supra* note 88. See also BELMONT REPORT, *supra* note 1, and APA Principles, *supra* note 16, at 633 (Preamble) (emphasizing respect for human dignity and personal autonomy).

270. If prospective participants are unduly alarmed, the principle of beneficence would be doubly violated. The good of the individual would be compromised by unnecessary stress, and social welfare would be adversely affected by the difficulty in recruiting participants and, therefore, conducting research. Insofar as concerns of participants are justified, the solution should be, of course, to diminish risk, not to hide it.

constructed in such a way that no promise or expectation of privacy is created for participants, a researcher's case for maintaining confidentiality might be weakened,²⁷¹ and participants therefore placed at greater risk of harm. On the other hand, promises of confidentiality that are not based on any legal right may not be recognized and may result in liability to the researchers for voluntary breaches of such promises. The question to be resolved, then, is how all of these concerns can be balanced in an informed consent form. To supply guidance for resolving this issue, the legal requirements for informed consent²⁷² will be presented, along with suggested strategies for complying with these specifications.

For research that requires informed consent, consent must be obtained under circumstances that provide the participant sufficient opportunity to consider whether or not to participate, and minimize the possibility of coercion or undue influence.²⁷³ The information that is given to the participant must be in understandable language.²⁷⁴ The consent process may not be used to obtain express or implied waivers of participants' rights in the event that the investigator or research institution incurs liability.²⁷⁵

The basic requirement for informed consent is the provision of whatever information may be relevant to a particular participant's decision whether to participate.²⁷⁶ The beginning point in this calculus is provision of information about what the investigator proposes to do and why he or she is conducting the study. When, as is most often the case, the study is not for the direct benefit of the participants, such information is relevant to potential participants' decision whether the research is worthy of their investment of time and assumption of risk. In their subjective value system, is the area of research one which is worthy of study? Are the specific procedures to be employed ones that the individual participants idiosyncratically find enjoyable, interesting, boring, painful, or repugnant? Accordingly, informed consent requires disclosure of the nature and purpose of the research:

(1) There must be a statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental.²⁷⁷

In addition to knowledge of whether the research is of a sort in which the prospective participant might have an interest, knowledge

271. See *supra* note 240 and accompanying text.

272. 45 C.F.R. § 46.116 (1984).

273. *Id.* See also OPRR, *supra* note 87 at 2.

274. 45 C.F.R. § 46.116 (1984).

275. *Id.* See also OPRR, *supra* note 87, at 2.

276. APA Principles, *supra* note 16, at 638 (Principle 9d). See generally J. KATZ, *supra* note 3; INFORMED CONSENT, *supra* note 85, at 13-15.

277. 45 C.F.R. § 46.116(a)(1).

of potential risks and benefits is necessary for participants to reach a reasoned decision about whether to participate.²⁷⁸ Therefore:

(2) There must be a description of any reasonably foreseeable risks or discomforts to the subject.

(3) There must be a description of any benefits to the subject or to others that may reasonably be expected from the research.²⁷⁹

Although the specific risks to be incurred will obviously vary, research on AIDS generally includes risks resulting from breaches of confidentiality, if they occur. For most psychosocial research on AIDS, there also may be some discomfort from consideration of emotionally laden topics, including concerns about AIDS itself. The potential benefit of research may be more difficult to gauge, because serendipitous findings may be the ones that have the most impact. It should certainly be possible, however, to give participants a general sense of what the investigator hopes to accomplish through the research (e.g., to learn more about how stress and the immune system are related).

If as a result of their involvement participants will be deprived of benefits, this point should also be made clear. In particular, research on efficacy of specific preventive or therapeutic interventions may necessitate at least temporary deprivation of other interventions.²⁸⁰ When such withholding of services is part of the research design, sufficient information about the risks and benefits of those services also must be given to permit potential participants to make an informed decision:

(4) There must be disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.²⁸¹

Investigators are also required to inform potential participants about the procedures for maintaining confidentiality and the limits on privacy:

(5) There must be a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.²⁸²

Having been informed, pursuant to the second requisite, about any harms that may accrue from a breach of confidentiality, potential participants may now calculate how likely such a harm is to occur. Full disclosure of the limits of confidentiality protects the participant and

278. INFORMED CONSENT, *supra* note 85, at 12.

279. 45 C.F.R. § 46.116(a)(2)-(3).

280. See generally Breger, *Randomized Social Experiments and the Law* in SOLUTIONS, *supra* note 214, at 17; McLean, *The Effect of Informed Consent on the Acceptance of Random Treatment Assignment in a Clinical Population*, 11 BEHAV. THERAPY 129 (1980).

281. 45 C.F.R. § 46.116(a)(4) (1984).

282. *Id.* at § 46.116(a)(5). See also OPRR, *supra* note 87, at 3; APA Principles, *supra* note 16, at 635-36 (Principles 5 & 9j); Bayer, *supra* note 141, at 3 (Recommendations 3), 6 (Recommendation 17).

the researcher. A claim of misrepresentation can be made against researchers who promise total confidentiality but know that there is a possibility that a court order may force such disclosure. The researcher must be candid about potential breaches of confidentiality, while still stressing to the participant that every measure possible will be taken to protect confidentiality.²⁸³

Consent forms are commonly drawn narrowly to focus on the actual research procedures that are to take place. Researchers have only rarely concerned themselves adequately with confidentiality issues that may arise even after the study is completed. This disregard for potential, if remote, breaches of confidentiality can no longer be allowed to occur, particularly in AIDS research where disclosures can be devastating to the participants. It is clear that under current law absolute guarantees of confidentiality cannot be made. Participants should be informed whether information will be retained after the research is completed, for how long, in what form (e.g., whether identifiers will be retained), and with what safeguards (e.g., certificates of confidentiality), if any. Perhaps most important, all reasonably foreseeable breaches of confidentiality should be described.²⁸⁴

Such potential disclosures of data fall into four categories. First, there are disclosures that involve minimal risk to participants' privacy and may occur without consent or further notice. For example, unidentified, summarized information may be disclosed to other researchers through publication. Second, disclosures may occur that do involve significant threats to privacy, but do not require participants' consent. In these instances (e.g., subpoena), participants should be notified of the impending disclosure if their identities remain known to the researcher, so that they themselves may attempt to take protective action. Third, there are disclosures requiring consent to which consent is being given by virtue of the agreement to participate in the study. For example, if the researcher makes clear an intention to share data with public health authorities, participants may decide whether to participate in the study under such a condition. Care should be taken, however, not to make potential disclosures so broad that participants cannot make an informed decision.²⁸⁵ A fourth type

283. Bayer, *supra* note 141, at 3 (Recommendations 3, 6 & 17).

284. There is, of course, a judgment call as to what level of probability rises to "reasonably foreseeable." In respect for participants, however, investigators should err on the side of overinclusiveness in describing risks. In view of the common legal jeopardy of participants in AIDS research, the possibility of subpoena should be acknowledged, in the absence of clear legal protection (e.g., a privilege statute).

285. If, for example, participants are asked whether they wish their data communicated to other researchers whenever combination of data sets may be useful, the request is probably too vague for participants to make an informed judgment. Participants (and researchers) cannot validly predict risks and benefits of possible future disclosures.

of disclosure is one that will occur only with the participant's consent, but for which consent is not now being given. In such a circumstance, participants obviously must be contacted again, so participants must at least give informed consent to maintenance of identifying information and future intrusions by the researcher.

Researchers also must inform potential participants about remedies that will be available if participants are harmed as a result of their involvement in the study:

(6) For research involving more than minimal risk, there must be an explanation as to whether any compensation or medical treatments are available if injury occurs and if so, what they consist of, or where further information may be obtained.²⁸⁶

Thus, participants should be notified of any mental health services that will be provided by the researchers in case of distress resulting from the study. Information also may be provided about other sources of help, including assistance for psychosocial concerns related to AIDS, substance abuse, and so forth, regardless of distress resulting from the study itself.

Finally potential participants should be assured of the voluntariness of the research and their right to make an informed decision:

(7) There should be an explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.²⁸⁷

(8) There should be a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participants are otherwise entitled, and that the participants may discontinue participation at any time without penalty or loss of benefits to which they are otherwise entitled.²⁸⁸

B. Procedures for Informed Consent

Investigators, granting agencies, and IRBs should give careful thought to the procedures for obtaining informed consent, as well as the substance of what is disclosed. In that regard, written forms are not necessarily the optimal means of providing information and recording consent. Obviously, written forms provide a largely indisputable record of the consent, so that they provide some protection to the

286. 45 C.F.R. § 46.116(a)(6) (1984). *But cf.* APA Principles, *supra* note 16, at 638 (Principle 9i) (*requiring* treatment for research-related injuries).

287. 45 C.F.R. § 46.116(a)(7) (1984). *See also* APA Principles, *supra* note 16, at 638 (Principle 9g).

288. 45 C.F.R. § 46.116(a)(8) (1984). *See also* APA Principles, *supra* note 16, at 638 (Principle 9f); CPHPR, *supra* note 88, at 26, col. 3; OPRR, *supra* note 87, at 3. Obviously, this provision — and others — do not apply if in fact participation is compelled under the police power to protect the public health. In such an instance, full disclosure of the requirements, risks, and benefits still is deserved, however. *See* Bayer, *supra* note 141, at 7 (Recommendation 21).

researcher (assuming that full disclosure of relevant information is made). However, there are two countervailing considerations.

First, participants often do not comprehend or attend carefully to written forms.²⁸⁹ In view of the significance of the decision to be made, the investigator bears a special obligation to ensure that consent is truly informed. If written forms are used, special attention should be given to their readability.²⁹⁰ The written forms should be supplemented by oral discussion,²⁹¹ and consideration should be given to the use of two-part consent forms.²⁹²

Second, consent forms may themselves represent a threat to privacy. If identifying information is removed from research data, the forms may represent the only identifiable record of participation. If the forms are then disclosed, participants may be individually vulnerable to subpoena or other inquiry about their health, sexual behavior, drug use, or other private behavior that may be inferred from the nature of the study. When consent forms do represent a demonstrable threat to privacy, the federal regulations permit consent without such documentation.²⁹³

Of course, some situations do not legally require informed consent at all.²⁹⁴ One exception to required informed consent applies to research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens. This will be true where these sources are publicly available, or if the information is recorded by the investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.²⁹⁵ This exception may apply to the use of medical records.²⁹⁶ However, even without legal requirements, the researcher should be aware of the possible harms that could be caused by the inadvertent or deliberate disclosure of personal information from such records. If

289. INFORMED CONSENT, *supra* note 85, at 26-28 and cites therein.

290. For easily applicable scales to test readability, see Grundner, *Two Formulas for Determining the Readability of Subject Consent Forms*, 33 AM. PSYCHOLOGIST 773 (1978). Instructions for simplifying language and syntax can be found in A. ELWORK, B. SALES & J. ALFINI, *WRITING UNDERSTANDABLE JURY INSTRUCTIONS* (1982).

291. Roth, Lidz, Meisel, Soloff, Kaufman, Spiker & Foster, *Competency to Decide about Treatment or Research: An Overview of Some Empirical Data*, 5 INT'L J.L. & PSYCHIATRY 29, 48 (1982).

292. A two-part consent form includes questions at the end to ensure that potential participants understand the information that has been disclosed. Such a form is useful, of course, only if the investigator takes it seriously and does not "prompt" the correct answers.

293. 45 C.F.R. § 46.117(c)(1) (1984). See also Bayer, *supra* note 141, at 7 (Recommendation 19).

294. 45 C.F.R. § 46.117(c) (1984).

295. *Id.* at § 46.101(b)(5).

296. Bayer, *supra* note 141, at 7 (Recommendation 20).

possible, the researcher should contact the person whose file is to be used and obtain consent for such use, if this is can be done without violating the person's privacy. If the patient cannot be contacted, the researcher should either not use the file at all, not use any identifying information, or use every safeguard possible to protect such information. The researcher should also be prepared to accept the responsibility and consequences for any harmful disclosures. A solution to this problem would be for physicians, and others who retain medical files of persons with AIDS, to inform their patients that their records may be used for research. Ideally, physicians should obtain patients' consent before each such disclosure.²⁹⁷

297. See generally Gordis & Gold, *Privacy, Confidentiality, and the Use of the Medical Records in Research*, 207 Sci. 153 (1980).