

# THE NATIONAL ACADEMIES

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Dr. Daniel Federman, Chair  
Committee on Assessing the System for Protecting  
Human Research Participants  
Institute of Medicine  
The National Academies  
Washington, DC 20418

Dear Dr. Federman:

The current system for protecting human participants in research is widely perceived to be in need of review and improvement (see, e.g., U.S. Department of Health and Human Services, 1998; American Association of University Professors, 2001). Concerns are of two types. One is the potential for serious harm to participants and the need to better protect them from such harm.<sup>1</sup> The other is unnecessary burdens that may result from applying review standards for high-risk research to low-risk studies—burdens on institutional review boards (IRBs), which are the primary bodies for reviewing and monitoring research with human participants; on researchers; and sometimes on participants themselves.<sup>2</sup>

In a climate of heightened scrutiny of IRB procedures, the Institute of Medicine (IOM) established your committee in fall of 2000, with funding from the U.S. Department of Health and Human Services and the Greenwall Foundation. In June 2001 the Committee on National Statistics of the National Research Council, in collaboration with the Board on Behavioral, Cognitive, and Sensory Sciences and Education, established our study panel, the Panel on IRBs, Surveys, and Social Science Research.

This letter is written to provide input to your committee for use in your final report. It comments on issues of human participant protection in research in the domain of the social, behavioral, and economic sciences (SBES) and outside the domain of biomedical research. In fact, research methods are rarely unique to either domain, although some methods, such as interviews, are more typically used in SBES research than in biomedical research, while the reverse is true for other methods, such as double-blind experiments.<sup>3</sup> Some of the differences between the two domains in research methods and in the frequency and nature of their use create issues of human participant protection for one domain that may receive less emphasis in the other. This letter provides an SBES perspective—on the assumption that your committee by design is more concerned with biomedical research.

In the letter we primarily address field, laboratory, and archival research conducted by such typical SBES methods as mail, telephone, and in-person surveys, structured interviews, participant observation, laboratory

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<sup>1</sup>This concern has been heightened, for example, by the death of Jesse Gelsinger, a participant in an experimental gene therapy study at the University of Pennsylvania. For a summary of pertinent news articles, see <http://www.ups.upenn.edu/ihtag/otcinfo.html>.

<sup>2</sup>This concern has been heightened by regulatory actions that temporarily shut down all research, regardless of risk, at two universities, Johns Hopkins University (see [Keiger](#) and [De Pasquale](#), 2002) and Duke University (see Stout, 1999).

<sup>3</sup>For example, 49 percent and 59 percent of SBES research reviewed by a sample of university IRBs involved interviews or self-administered questionnaires, respectively, compared with 23 percent and 21 percent, respectively, of biomedical research. In contrast, 27 percent, 25 percent, and 21 percent of biomedical research involved invasive procedures, double-blind experiments, and placebo administration, respectively, compared with 3 percent, 3 percent, and 1 percent, respectively, of SBES research (Bell, Whiton, and Connelly, 1998:Fig. 8).

research, and other methods that ordinarily pose low risk to participants. By “low risk” we refer to the definition in federal regulations, namely, that a study has a low probability of causing physical, psychological, or economic harm to participants and that the nature of the harm is minimal and no more than is normally encountered in daily life (see the Common Rule, Title 45, *Code of Federal Regulations* (CFR), subpart A, sec 46.102i, revised June 18, 1991).

We focus on low-risk SBES research for two reasons. First, as your committee and our panel deliberated, it became clear that your group’s primary focus is on high-risk research, regardless of domain. Second, many of the concerns raised about the protection of human participants in SBES research relate to low-risk research. We do not imply thereby that SBES research is always low risk, nor that biomedical research is always—or even often—high risk. Studies of IRB operations report that high percentages of all types of research—biomedical, social, and psychological—are deemed to be low risk (Gray, Cooke, and Tannenbaum, 1978:1096; Bell, Whiton, and Connelly, 1998:20).

The final report at the conclusion of our work (planned for fall 2002) will discuss in more detail issues of defining risk and other aspects of ethical review of SBES research for a broad audience of IRBs, researchers, and relevant federal agencies. In that report we will address all three basic principles of protection for human research participants, as articulated in the Belmont Report (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979). These principles, which apply to all research domains and to low-risk as well as high-risk protocols, include respect for persons (respecting the choices of autonomous individuals and protecting those who are immature or incapacitated); beneficence (minimizing harm and maximizing benefits); and justice (fairness in the selection of research participants with regard to the distribution of the burdens and benefits of research).

This letter provides the panel’s initial recommendations on four topics: protection of confidentiality of information obtained from human research participants; requirements for informed consent, particularly for advance written consent; procedures for determination of exempt research and for expedited review of low-risk research; and system-level issues, such as training of researchers and accreditation. The recommendations were developed from an SBES perspective. Some of them may pertain to biomedical research, but we do not make that judgement. Many of the recommendations have benefited from the work of other groups that are active in considering the protection of human participants in SBES research, such as the Behavioral and Social Science Working Group of the National Human Research Protections Advisory Committee<sup>4</sup> and the National Science Foundation’s Social, Behavioral, and Economic Subcommittee for Human Subjects.<sup>5</sup>

Several recommendations call for the Office for Human Research Protections (OHRP) in the U.S. Department of Health and Human Services (DHHS) to provide guidance to IRBs, in recognition of the leadership role that OHRP is charged with playing in the federal system. OHRP, which was established in June 2000, has responsibilities that include not only monitoring the operations of IRBs that review DHHS-funded research, but also providing guidance on human research participant protection for the federal and non-federal sectors, developing educational programs, and exercising leadership for human participant protection for the U.S. government in cooperation with other federal agencies (67 *Federal Register*, 10217, March 6, 2002). The director of OHRP serves as the *ex officio* chair of the Human Subjects Research Subcommittee of the White House Office of Science and Technology Policy.<sup>6</sup>

## PROTECTING CONFIDENTIALITY

Ensuring that data collected under a pledge of confidentiality are protected from disclosure is a long-accepted requirement of research with human participants. Indeed, for much research using typical SBES methods, the major risk is that of inadvertent disclosure—either during collection, processing, or storage of the original data or through identification of participants in data files that are made available for secondary analysis.

Protecting against a breach of confidentiality is imperative when it could cause substantial harm to a research participant—for example, denial of health insurance or employment because of information supplied about a medical condition. Even if no or only minimal harm is likely, a confidentiality breach could undermine the credibility of researchers and needlessly reduce the willingness of people to participate in research.

Although there can never be a 100 percent guarantee that confidentiality will be maintained, state-of-the-art computer science and statistical methods can reduce to minimal levels the risk of inadvertent identification. OHRP

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<sup>4</sup>See <http://www.asanet.org/public/humanresearch>.

<sup>5</sup>For information, contact Stuart Plattner, NSF Human Subjects Research Officer, [splattne@nsf.gov](mailto:splattne@nsf.gov).

<sup>6</sup>See <http://ohrp.osophs.dhhs.gov>.

can usefully provide guidance to IRBs by documenting and promulgating good practices for maintaining confidentiality at every stage of the research process and for informing research participants about the scope and limits of confidentiality protection that is offered them.

For some sensitive studies, such as those in which a participant may report illegal behavior, it is particularly important that researchers understand their responsibilities and limits with regard to confidentiality protection and that IRBs review carefully the proposed procedures for preventing disclosure. In some cases, it may be important to obtain a certificate of confidentiality to protect the data from subpoena in legal proceedings.<sup>7</sup>

Another class of studies for which confidentiality protection poses special problems comprises longitudinal panels in which participants are interviewed more than once over a period of time. Researchers must retain identifying information for individual participants to be able to locate them for subsequent interviews; also, panel data are typically richer in subject content than one-time, cross-sectional studies. Both of these features require careful consideration of procedures to minimize the risk of disclosure while not unnecessarily limiting the usefulness of the data for research.

Because the use of new methods of data collection and dissemination, such as the Internet, is increasing the amount of readily available data and the potential for linking data files, continued research and development of methods for confidentiality protection is needed. Also needed is continued work on administrative arrangements (e.g., secure enclaves) that permit research access to data for which widespread public dissemination is deemed too risky (see National Research Council, 1993).

**Recommendation 1:** The Office for Human Research Protections and other relevant federal agencies, working with professional associations in the social, behavioral, and economic sciences, should document and promulgate good practices for using state-of-the-art computer science and statistical methods to protect the confidentiality of SBES data that are made available for secondary analysis. OHRP should also provide guidance on good practices for protecting confidentiality at every stage of the research process.

**Recommendation 2:** When reviewing research protocols, IRBs should pay close attention to the adequacy of proposed plans to safeguard confidentiality in the collection, processing, analysis, dissemination, and storage of SBES data and request improvements as necessary. Because some research exposes participants to risks of harm if even their participation becomes known to others, IRBs should carefully review the adequacy of proposed procedures for preventing such disclosure.

**Recommendation 3:** Federal funding agencies should sponsor research on procedures and techniques to protect the confidentiality of SBES data that are made available for research use.

**Recommendation 4:** Public and private data archives that provide data sets on individuals (microdata) to SBES researchers for secondary analysis should keep abreast of disclosure risks and state-of-the-art mechanisms to control disclosures. They should regularly update control mechanisms to protect the data that they house and be able to certify to researchers that the data they provide for secondary use have been rendered acceptably anonymous.

## INFORMED CONSENT

Informed consent is fundamental to the ethical conduct of research with human participants. Current federal regulations include detailed requirements for the kinds of information to be conveyed in the informed consent process and the documentation of consent. The regulations also include provisions for waiving or modifying some or all of these requirements, such as written consent, under specified conditions (45 CFR, sec. 46.116, 117), many of which commonly apply to SBES research.

It appears, however, that some IRBs do not make appropriate use of the flexibility in the regulations. A rigid practice of requiring advance written consent for all research protocols, regardless of method, level of risk, and population studied, can hamper participation and yet not offer more protection to participants than other consent procedures. For example, federal statistical agencies have for decades obtained respondents' cooperation with

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<sup>7</sup>Certificates of confidentiality for research on sensitive topics, regardless of funding source, can be obtained from the National Institutes of Health (see <http://grants.nih.gov/grants/policy/coc/index.htm>).

voluntary mail, telephone, and in-person surveys by procedures other than signed documents obtained in advance. These procedures typically include a prescribed introductory statement by the interviewer about the purpose of the survey and informing the respondent that he or she may break off the interview at any time; they also include, when feasible, an advance letter about the survey. There is no evidence of adverse effects on respondents of such procedures. Indeed, there is evidence that respondents do not view signing a written consent form as protecting their interests.<sup>8</sup>

Other types of research for which written informed consent may not be feasible or appropriate include studies of populations that are not literate or that are unable or unwilling to sign a written consent form but would agree to participate through another consent process. In yet other cases, a signed consent form may be the only identifier of a participant and may thereby present a risk of disclosing his or her participation in a study that would otherwise not exist.

Most, if not all, of the issues surrounding informed consent have been raised by others,<sup>9</sup> and current federal regulations have tried to be sensitive to them. Thus, the Common Rule permits waiver of written consent under certain circumstances (45, CFR, sec. 46.117c). However, in practice, implementation of effective informed consent procedures that accommodate varying situations has been difficult to attain, for complex reasons. One reason involves the organizational setting of most IRBs, which are usually nested within larger institutions faced with pressures to have verifiable evidence for informed consent. Consequently, IRBs may require signed consent forms for all research, even when other consent processes or a waiver of consent would be more appropriate, in order to obtain documentation that is easily archived and retrieved for defending the procedure.

**Recommendation 5:** As provided by federal regulations, IRBs should consider a variety of procedures for obtaining informed consent and grant waivers of written consent when to do otherwise would inhibit useful SBES research with no appreciable added protection for the participants.

A related concern about written consent procedures (which may also apply to other forms of consent) is that they may not convey what research participants need to know to make an informed decision to participate in a research study and to understand that their participation is voluntary. Research has documented the difficulties of understanding the benefits, harms, and risks of harm of biomedical research as described in consent forms, which are often highly technical in nature (see, e.g., David et al., 1998; Goldstein et al., 1996; Taylor et al., 1998). We imagine that similar problems may affect consent processes in some kinds of SBES research as well. The National Institutes of Health recently announced a program to fund research on ethical issues in human studies, including research on informed consent procedures.<sup>10</sup> We commend this initiative and urge other funding agencies to sponsor studies of informed consent for different types of research and study populations.

**Recommendation 6:** Federal funding agencies should sponsor research on procedures for obtaining and documenting informed consent that will facilitate comprehension of research benefits, harms, and risks of harm for different types of SBES research and populations studied.

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<sup>8</sup>For example, an IRB that reviews surveys conducted by the National Center for Health Statistics (NCHS) a few years ago required advance written consent for participation in the ongoing National Health Interview Survey, although no evidence existed that lack of advance written consent misled participants about the nature of the research in more than 30 years of conducting the survey, and a pilot test estimated that such a requirement would add significant costs to the data collection. From the results of the pilot test, the IRB agreed to a set of procedures, implemented nationwide starting in July 1999, whereby the respondent may sign at the beginning of the interview, after hearing some questions, or at the end of the interview. If the respondent is willing to participate, but does not want to sign, the interviewer may sign the consent form. Based on subsequent research with respondents indicating that they do not see signing a written consent form as offering them protection, NCHS is considering applying for a waiver of that requirement (personal communication, Jennifer Madans, NCHS).

<sup>9</sup>Complex issues, which we do not consider in this letter, surround informed consent procedures in studies of young children and other populations for whom permission must be sought from another party (e.g., a parent or guardian); also, in determining when it is necessary to seek consent from nonparticipating individuals about whom research participants are asked to supply information (e.g., when a survey respondent is asked for information on relatives).

<sup>10</sup>See <http://grants1.nih.gov/grants/guide/pa-files/PA-02-103.html>.

## EXEMPT RESEARCH AND EXPEDITED REVIEW

Federal regulations exempt some types of research involving human participants from IRB review, and some studies, although involving interaction with humans, do not meet the regulatory definition of “human subjects research” (see 45 CFR, sec. 46.101,102). For studies for which IRB review is appropriate, the regulations provide for expedited review of many types of low-risk studies by the IRB chair or other member(s) to whom the IRB delegates the approval function. (The current list of types of studies that may receive expedited review is in 63 *Federal Register*, 60364, November 9, 1998.) The IRB chair or designee determines whether a particular protocol is exempt or may be reviewed using the expedited procedure.

In response to tragic incidents in biomedical research and increased scrutiny of IRB operations, IRBs appear to be increasingly applying review procedures that are appropriate for high-risk research to studies that are low risk, thereby placing unnecessary burdens on researchers, IRBs, and, sometimes, human participants. A recent survey of IRBs found that one-half or fewer research protocols eligible for exemption are in fact exempted from review and that full IRBs convene to review anywhere from 15 to 83 percent of low-risk protocols that are eligible for expedited review (Bell, Whiton, and Connelly, 1998:Figs. 15, 16). Full board review for such projects imposes delays and adds needlessly to the person-hours required for the review process. For example, Bell, Whiton, and Connelly (1998:Fig. 33) found that 71 percent of expedited reviews are completed in less than 30 days (18% in less than a week), while only 49 percent of full board reviews are completed as expeditiously (and only 5% in less than a week).

Although IRBs are allowed to exceed federal requirements for review of protocols, we believe that the level of review should be commensurate with the level of risk. Given rising workloads for IRBs in terms of numbers and complexity of research protocols (e.g., more multisite projects), it behooves IRBs to concentrate scarce board member and researcher resources on high-risk projects. We believe that added guidance from OHRP could help IRBs make more appropriate choices of level of review for SBES research.

Examples of research that the panel believes should not be considered “human subjects research” include (1) organizational surveys seeking information only about the organization (e.g., number of employees at a business) and not about the individual respondent, and (2) secondary analyses of aggregate (tabular) data when the data are not provided at the individual level of analysis and information about individuals cannot be recovered from the tabulations.

Examples of research that the panel believes are clearly exempt from IRB review under current regulations include secondary analyses of public-use data for individuals (microdata) obtained from suppliers, such as federal statistical agencies and data archives, that regularly follow good practices to minimize the risk of identification of individuals (see recommendations 1 and 4 above). Analyses of microdata from such suppliers as the U.S. Census Bureau, which follows stringent disclosure review and protection procedures, should have blanket exemptions from review.

**Recommendation 7:** OHRP, working with professional associations in the social, behavioral, and economic sciences, should develop clear examples of common social, behavioral, and economic research designs, methods, and procedures that are not to be regarded as “human subjects research” or that are clearly exempt from review. OHRP should include these examples in guidance to IRBs to amplify the existing regulations.

The current list of types of research that may be reviewed by an expedited procedure (so long as the research is low risk) includes many kinds of specific medical procedures, such as electrocardiograms. It also includes broad categories of SBES research, such as surveys, oral histories, and focus groups. We believe it is important to add *specific* SBES procedures to the list to encourage IRBs to use expedited review procedures for low-risk SBES research.

Examples of specific SBES procedures that could be added to the existing list for using the expedited review procedure are experiments that test responses to noninvasive auditory or visual stimuli of competent adult participants; experiments that study decision-making with competent adult participants; and surveys of competent adults that include standard demographic and socioeconomic questions and other questions (e.g., attitudes) for which there is no reasonable expectation of harm (e.g., from experience with the same or similar questions in other surveys).<sup>11</sup> The importance of providing specific examples is affirmed by evidence that IRBs are most likely to expedite the review of low-risk studies that use *specific* procedures that are currently in the approved list (e.g.,

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<sup>11</sup>Federal regulations require extra protections for children, prisoners, pregnant women, and fetuses.

studies that obtain nail and hair clippings or dental plaque), in contrast to studies that fall under general categories (e.g., drugs and medical devices) (see Bell, Whiton, and Connelly, 1998:Fig. 16).

**Recommendation 8:** OHRP, working with professional associations in the social, behavioral, and economic sciences, should amplify the existing list of categories of research that may be reviewed using the expedited review procedure. The next revision of this list should include greater specificity of the types of SBES research design and methods that are eligible for expedited review.

## SYSTEM ISSUES

### Data on IRB Operations

Several studies have been conducted over the past few decades on the operation of the IRB system—see, for example, Bell, Whiton, and Connelly (1998); U.S. General Accounting Office (1996); Sieber and Baluyot (1992); Cooke, Tannenbaum, and Gray (1978; see also Gray, Cooke, and Tannenbaum, 1978). It is difficult to compare the results of the different studies, and some are quite limited in sampling frame and sample size.

In order to have a richer set of data on IRB operations and to track the strengths and weaknesses of the IRB system over time, we believe there is a need for a continuing survey of IRBs, with a longitudinal component. Our recommendation pertains specifically to the need for a continuing survey of IRB characteristics and procedures with respect to SBES research. In our final report, we plan to analyze further the data from existing studies of IRBs and to provide details on the requirements for a useful data system.

**Recommendation 9:** OHRP and other relevant agencies, working with professional associations in the social, behavioral, and economic sciences, should develop an ongoing survey of IRB composition and practices, as an informational resource that can help assess strengths and weaknesses of the system for protecting human participants in SBES research. The design should permit analysis of review practices for SBES research by type of IRB (all fields, SBES fields only), representation of SBES expertise on IRBs, and related issues.

### Accreditation

One of the major tasks of the IOM committee is to recommend standards for accrediting human research protection programs. The committee's initial recommendations included that "[t]he first step is implementation of pilot programs to test standards, establish accreditation processes, and build confidence in accrediting organizations" (Institute of Medicine, 2001:53). We support the plan to evaluate accreditation standards through the use of pilot tests. We also agree with the committee that the accreditation process should accommodate organizations involved in research beyond the traditional academic health centers and Veterans Administration and with models other than clinical research, a position that has been adopted by the Association for the Accreditation of Human Research Protection Programs.<sup>12</sup> However, the pilot studies that are in progress (see Institute of Medicine, 2001) do not encompass SBES research. For this reason, we consider it premature to determine whether accreditation of IRBs would improve protection for human participants in SBES studies.

**Recommendation 10:** Pilot testing that is currently under way for a voluntary system for IRB accreditation should be expanded to include social, behavioral, and economic science research settings. Only when the program has been shown to be effective in such settings should proposals be developed for expanding accreditation to review of social, behavioral, and economic science research.

### Training

The success of the system for protection of human research participants in SBES research depends on the proactive ethical behavior of all of the relevant actors—principal investigators and other researchers and their

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<sup>12</sup>For more information, see <http://www.aahrpp.org/principles.htm>.

professional associations, institutions of higher education and other research organizations and their IRBs, federal regulators and funding agencies. With respect to universities, we agree with the assertion by the Association of American Universities (2000:4) that senior managers "should state clearly to their entire campus communities the importance of conducting human subjects research in accordance with the highest standards of ethical conduct." But more than the top managers can and should provide leadership. Academic departments must incorporate ethical principles into the education they provide, and professional associations must regularly review and update their codes of professional ethics with regard to human research participant protection. Thorough, continuing training for researchers and IRB members is critical for the effective operation of the human research participant protection system and its continued improvement. For long-run success, the ethics of protection must be woven into the fabric of the research preparation of all scientists.

**Recommendation 11:** Academic institutions, working with scientific and professional associations in the social, behavioral, and economic sciences, should develop in-depth training curricula and materials that are customized for social, behavioral, and economic scientists regarding the ethical involvement of human research participants. OHRP should similarly develop for IRBs customized training materials that focus on review of SBES research.

## CONCLUSION

Our panel looks forward to developing a full agenda for research and practice to improve the operation of the IRB system for social, behavioral, and economic science research. Such a system should provide full protection for human research participants and, at the same time, promote a level of review commensurate with the level of risk to facilitate the conduct of high-quality, ethical research.

Sincerely yours,

Cora Marrett, *Chair*  
Panel on IRBs, Surveys, and Social  
Science Research

Attachments:  
References  
Roster of Panel Members

## References

- American Association of University Professors  
2001 Protecting human beings: Institutional review boards and social science research. *Academe* 87(3):55-67.
- Association of American Universities  
2000 *Report on University Protections of Human Beings Who Are the Subjects of Research*. Report and recommendations from AAU's Task Force on Research Accountability. Washington, D.C.: Association of American Universities (June 28).
- Bell, J., J. Whiton, and S. Connelly  
1998 *Evaluation of NIH Implementation of Section 491 of the Public Health Service Act, Mandating a Program of Protection for Research Subjects*. Report prepared under a National Institute of Health contract, N01-OD-2-2109. Washington, D.C.: U.S. Department of Health and Human Services.
- Cooke, R.A., A.S. Tannenbaum, and B.H. Gray  
1978 A survey of institutional review boards and research involving human subjects. Pp. 293-302 in *Report and Recommendations on Institutional Review Boards, Appendix*. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. Washington, D.C.: U.S. Government Printing Office (September).
- Davis, T.C., R.F. Holcombe, H.J. Berkel, S. Pramanik, and S.G. Divers  
1998 Informed consent for clinical trials: A comparative study of standard versus simplified forms. *Journal of the National Cancer Institute* 90(9):668-674.
- Goldstein, A.O., P. Frasier, P. Curtis, A. Reid, and N.E. Kreher  
1996 Consent form readability in university-sponsored research. *Journal of Family Practice* 42(6):606-611.
- Gray, B.H., R.A. Cooke, and A.S. Tannenbaum  
1978 Research involving human subjects. *Science* 201(4361):1094-1101.
- Institute of Medicine  
2001 *Preserving Public Trust: Accreditation and Human Research Participant Protection Programs*. Committee on Assessing the System for Protecting Human Research Subjects, Board on Health Sciences Policy. Washington, D.C.: National Academy Press.
- Keiger, D., and S. De Pasquale  
2002 Trials & tribulation. *The Johns Hopkins Magazine* 54(1):28-41.
- National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research  
1979 *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*. Washington, D.C.: U.S. Government Printing Office. Available: <http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm>.
- National Research Council  
1993 *Private Lives and Public Policies: Confidentiality and Accessibility of Government Statistics*. Panel on Confidentiality and Data Access. G.T. Duncan, T.B. Jabine, and V.A. de Wolf, eds. Committee on National Statistics and Social Science Research Council. Washington, D.C.: National Academy Press.
- Sieber, J. E., and R.M. Baluyot  
1992 A survey of IRB concerns about social and behavioral research. *IRB: A Review of Human Subjects Research* 14(2):9-10.
- Stout, D.  
1999 U.S., citing safety, suspends human research aid at Duke. *The New York Times*, May 12.
- Taylor, K.M., A. Bejak, and R.H.S. Fraser  
1998 Informed consent for clinical trials: Is simpler better? *Journal of the National Cancer Institute* 90(9):644-645.
- U.S. Department of Health and Human Services  
1998 *Institutional Review Boards: A Time for Reform*. Office of the Inspector General Publication No. OEI-01-97-00193. Washington, D.C.: U.S. Department of Health and Human Services. Available: <http://www.dhhs.gov/progorg/oei/reports/a275.pdf>.
- U.S. General Accounting Office

1996 *Scientific Research: Continued Vigilance Critical to Protecting Human Subjects*. GAO/HEHS-96-72. Washington, D.C.: GAO.

## **Panel on Institutional Review Boards, Surveys, and Social Science Research**

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