PROTECTING HUMAN BEINGS: INSTITUTIONAL REVIEW BOARDS AND SOCIAL SCIENCE RESEARCH

In November 1999 and May 2000, the American Association of University Professors convened meetings of representatives of the American Anthropological Association, the American Historical Association, the American Political Science Association, the American Sociological Association, the Oral History Association, and the Organization of American Historians to consider the experiences of social scientists and scholars in other academic disciplines whose research is subject to the government's rules for protecting human beings. The following draft report was prepared by the AAUP. The listing of the organizations above does not imply their endorsement of the current text. Comments on the text are encouraged and welcomed.[1]

Introduction

This report is about the government's rules for protecting human beings who are the subjects of social-science research.[2] These rules and the mechanisms for implementing them have been in place, in one form or another, for more than thirty years. They are a permanent feature of research institutions in the United States, and there are clear signs that their influence is expanding.

The government's system for regulating research involving human subjects was born out of fear that researchers might, whether wittingly or not, physically or mentally injure the human beings that they study. The government's system is meant, therefore, to limit professional choice insofar as it might otherwise result in harm to human subjects. In pursuit of this aim, the government imposes a regulatory burden on research institutions and their individual researchers. Whether the burden is reasonable depends upon several considerations, not the least of which is the application of the government's rules

---

[1]Correspondence can be addressed to Jonathan Knight, AAUP, 1012 14th Street, NW, Washington, DC 20005. E-mail: jknight@aaup.org.

[2]The social sciences encompass a wide array of academic specialties, but conventionally refer to the disciplines of anthropology, economics, geography, political science, psychology, and sociology. With apologies to historians, many of whom would not accept the designation of social scientist, this report will use the phrase social science to refer also to those branches of historical research that have been subject to the government's regulations.

to disparate academic fields of study, each with its own concepts and methods of research and standards of professional responsibility.

The report is addressed both to researchers in the social sciences and to those individuals in research institutions who are responsible for implementing the government's regulations. To some degree these categories overlap, most clearly when researchers serve on local committees that determine if a proposed project satisfies the government's requirements. The report rests on the assumption that researchers in their several capacities and administrative officers can benefit from more and better information about the government's evolving regulations and the challenge of applying them fairly and effectively to the social sciences.

This report is in four parts:

Part I, overview of concerns about the government's regulations, describes the concerns of social scientists that institutional review boards (IRBs) go too far in regulating their research, but also draws attention to the concerns of those critics of IRBs who believe that their authority must be expanded.

Part II, a preliminary matter: IRBs and academic freedom, considers whether the government's system for regulating human subject research itself violates the freedom of researchers to plan and carry out their projects as they deem appropriate.

Part III, the "common rule," the longest section of the report, describes and evaluates the government's regulations for protecting the human subjects of research and how they have been applied to the work of social scientists. There is comment on what needs to be done to improve the functioning of campus IRBs with respect to social-science research.

Part IV, conclusions, draws conclusions and offers them in the form of recommendations. The report's central conclusion is that IRBs, in carrying out their responsibilities, too often mistakenly apply standards of clinical and biomedical research to social-science research, to the detriment of the latter; its central recommendation is that IRBs can and should do more to take into account the pluralistic nature of academic research that is subject to their review.

Part I: Overview of Concerns About the Government's Regulations

In 1991, the Department of Health and Human Services issued a set of revised regulations for protecting the rights and welfare of human-research subjects.[3] These regulations were initially promulgated in 1981, and, in earlier major versions, in 1966 and 1974. The 1991 regulations--known as the Common Rule and subscribed to by sixteen other federal departments and agencies, among them the National Science Foundation, the Department of Agriculture, the Department of Education, and the Department of Defense--constitute the core regulatory structure for research involving human subjects that is funded by the federal government.[4]

Research institutions must comply with the Common Rule if their investigators are to be eligible for funding by one of the government agencies that subscribe to the Rule. The key element in the system of compliance is the requirement that the institution establish an IRB, which has the authority to approve, require modification of, or disapprove research that is subject to the Common Rule. A recent

---

[3]Part 46 (Protection of Human Subjects) of Title 45 (Public Welfare) of the *Code of Federal Regulations* [hereafter 46 *CFR*].

[4]Among the federal agencies that do not subscribe to the Common Rule is the National Endowment for the Humanities. Eighteen states and the District of Columbia have statutes for the protection of human subjects. Most of these laws focus on medical research or, more narrowly, on the treatment and care of the mentally ill. The states are: Arizona, California, Delaware, Florida, Iowa, Louisiana, Minnesota, Montana, New York, New Mexico, North Carolina, Oklahoma, Oregon, South Dakota, Tennessee, Texas, Vermont, and Virginia.

study prepared for the National Institutes of Health indicates that few research proposals are rejected outright by IRBs, but that fewer than twenty percent are approved as submitted.[5] For an IRB to approve a research project, it must ensure that the "risks to subjects are minimized," that the "risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and [to] the importance of the knowledge that may be reasonably expected to result," that the "selection of subjects is equitable," and that "informed consent [has been] sought from each prospective subject or the subject's legally authorized representative.'[6] The Common Rule identifies human-subject research which, although funded by the government, is exempt from IRB review, and it also enumerates categories of research that may be reviewed by IRBs under an expedited procedure. As of 2000, approximately 4,000 IRBs were operating in the United States mainly at universities, hospitals, and private research facilities. In 1995, between 35,000 and 45,000 investigators conducted human-subject research under IRB auspices.[7] The typical investigator has an appointment at a research university and has obtained the highest professional degree in his or her field of study. But the research projects of students, both undergraduate and graduate, are potentially subject to IRB review, and at some institutions student research comprises a significant portion of the proposals reviewed by IRBs.

The main impetus for the development of IRBs was concern about informed consent and risks

---

[5] *Evaluation of NIH Implementation of Section 491 of the Public Health Service Act, Mandating a Program for Protection of Research Subjects* (1998) [hereafter *Evaluation of NIH*]: V-10. According to the same report, thirty-seven percent of IRBs had used their authority to suspend or terminate approved research. The reasons for these actions included failure of the researcher to obtain approval to continue the study, and the use of procedures not approved by the IRB.

[6] 46 *CFR* 46.111.

[7] *Evaluation of NIH*, II-8 Also C. K. Gunsalus, *An Examination of Issues Presented by Proposals to Unify and Expand Federal Oversight of Human Subject Research* (Commissioned by the National Bioethics Advisory Commission), (September 1998): 9.

associated with clinical and biomedical research. This concern reached back to the Nuremberg Code of 1948, which established standards for judging physicians and scientists who had conducted experiments on concentration camp prisoners. Clinical and biomedical research currently accounts for approximately seventy-five per cent of all the research that is reviewed by IRBs.[8] Social-science research was included almost from the outset in the system of regulatory oversight, although there was also recognition from the beginning that, in the words of the surgeon general of the United States in 1966, "there is a large range of social and behavioral research in which no personal risk to the subject is involved."[9] But even research that is not funded by any of the seventeen federal agencies, and which the government therefore does not require to be evaluated under the Common Rule, has been subject to local IRB review, for institutions often apply the requirement of IRB review to all research involving human subjects. Approximately seventy-five percent of the largest American research institutions, which for the most part are research universities or hospital affiliates of universities, have voluntarily extended the IRB review system to all human-subject research.[10] The IRB policy at the University of Minnesota is typical. The "scope" of the IRB "charge is broad. Generally, any University research that uses humans, human tissue, surveys of human subjects, or human subjects' records requires IRB review, irrespective of its funding source."[11]

---

[8] *Evaluation of NIH*, II-11.

[9] Quoted in Bradford H. Gray, "The Regulatory Context of Social and Behavioral Research," in Tom L.Beauchamp, Ruth R. Faden, R. Jay Wallace, Jr., LeRoy Walters, eds., *Ethical Issues in Social Science Research* (Baltimore and London: The Johns Hopkins University Press, 1982): 331.

[10] Communication from Thomas Puglisi, Director, Division of Human Subject Protections, Office for Protection from Research Risks, Department of Health and Human Services, to Jonathan Knight, American Association of University Professors, July 23, 1999.

[11] www.research.umn.edu/subjects.htm.

Why universities have extended the jurisdiction of their IRBs is discussed later in this report, but their having done so helps explain what prompted several professional organizations in the spring of 2000 to ask their members about their experiences with IRBs: they were hearing from researchers who were surprised and concerned that their work and that of their students, although not funded by a federal department or agency, had to be reviewed by the campus IRB.[12] Responding to an informal survey of their members conducted by these organizations, some researchers gave good marks to their campus IRBs for drawing their attention to ethical issues and for improving their proposals. Others reported excessive delays in reviews of research proposals, failures of IRBs to follow federal regulations that apply to survey research and oral history, and members of IRBs having little familiarity with social-science research compared to what they know about clinical and biomedical research. Some worried that the regulatory structure could improperly restrain freedom of inquiry and the pursuit of knowledge, and others claimed that it had done so already.

Behind these concerns lie deeper ones. Researchers complained about "inappropriately applying a model used for science and medicine to historical research," about members of IRBs "more used to medical experiments than political science ones," and about IRBs using "models from biomedical research for anthropology." The model that these researchers had in mind is one in which vulnerable human beings (for example, the ill, poor, or incarcerated) are often subject to invasive medical procedures. By contrast, the research of most social scientists involving human subjects does not pose a threat of physical or mental harm to the subjects, who are usually in possession of their full faculties and

[12]The organizations were the American Anthropological Association, the American Association of University Professors, the American Historical Association, the American Political Science Association, the American Sociological Association, the Organization of American Historians, and the Oral History Association.

can be expected to safeguard their own interests. While the subjects of social-science research may experience unease, discomfort, or embarrassment, these are risks, in the words of the Common Rule, that are "ordinarily encountered in daily life." For these scholars, then, the Common Rule was established and has evolved within a clinical and biomedical framework that does not fit, or fits poorly, their research.

These various concerns are not simply the views of some disgruntled scholars unfamiliar with IRBs. They are shared by the leaders of their professional societies, too. In 1998, the Oral History Association, the American Historical Association, and the Organization of American Historians corresponded with approximately 700 IRBs to encourage them to take into account the standards of practice relevant to historical research in their evaluations of oral history projects. In the same year, the three organizations persuaded the government to include oral history among those research activities that IRBs can review under an expedited procedure.[13] Still more evidence of current concerns can be found in the testimony of researchers in April 2000 before the National Bioethics Advisory Commission charged with examining the adequacy of the federal system for protecting human subjects involved in research:

> The problems that emerge within anthropological research . . . have to do with human beings, not just as physiological specimens, but as social creatures living in families, clans, groups, tribes, or nations. . . .The risks and benefits to the people [that anthropologists study] are very different from those faced by subjects of biomedical research.[14]

---

[13]The "Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) Through an Expedited Review Procedure" are described in 63 FR 60363 (November 9, 1998). The codes of ethics of several organizations refer specifically to IRBs and the obligations their members may have under federal regulations. See, for example, American History Association, *Statement on Standards of Professional Conduct* (1991), American Sociological Association, *Code of Ethics* (1997), American Political Science Association, *Guide to Professional Ethics in Political Science* (1998), and Oral History Association, *Guidelines and Principles* (2000).

[14]Professor Murray L. Wax, anthropology, Washington University in St. Louis.

> Researchers who are not particularly sophisticated . . . [and] have not been through [the IRB] process feel confused and cynical, distrustful of the IRB and regulatory process because it really does not seem to apply to them. And, unfortunately, there are unsophisticated IRBs that are readily confused, very risk averse, very heavy handed.[15]

> Historians report that they have been told by IRBs to submit detailed questionnaires prior to conducting any interviews; to maintain narrator anonymity both on tape and in their published work; and to either destroy their tapes or retain them in their private possession after their research project is completed. Each of these requests misconstrues oral history and violates fundamental standards of historical practice.[16]

These are not, it should be noted, new concerns. They echo issues raised in the late 1970s and early 1980s by scholars and organizations about the ethics of social-science research and governmental regulation of that research through IRBs.[17] But the fact that these concerns are familiar does not diminish their importance, for their recurrence, more than thirty years after the government announced its review requirements, points to continuing uncertainty about the credibility and authority of IRBs when they review social-science research. To the extent that an IRB acts, or is believed to act, unfairly, inconsistently, or arbitrarily, the more likely will confusion or conflict arise about an institution's commitment to uphold standards of ethics in human-subject research.

These renewed concerns by themselves would warrant another report on IRBs.[18] There is an

---

[15]Professor Joan E. Sieber, psychology, California State University, Hayward.

[16]Dr. Linda Shopes, Pennsylvania Historical and Museum Commission. The full texts of all the remarks submitted to the Advisory Commssion are at www.bioethics.gov.

[17]See, for example, the essays in Beuchamp, *et al*., and "Regulations Governing Research on Human Subjects: Academic Freedom and the Institutional Review Board," *Academe: Bulletin of the AAUP* (December 1981): 358-370.

[18]For earlier reports see n. 17.

additional consideration, however. Within and among the biomedical sciences and the social sciences, there are different views about the effectiveness of IRBs. The critics of IRBs who believe they go too far are matched by those who believe that they do not go far enough. The death of a patient in a gene-transfer study at the University of Pennsylvania in the fall of 1999 and possible financial conflicts of interest among clinical researchers have led to renewed calls for stronger guidelines to protect human subjects.[19] Even earlier, a 1996 General Accounting Office (GAO) report concluded that "oversight procedures are impaired by institutional review boards' heavy workloads and competing demands, limited funds for on-site inspections, the complexity and volume of research under review, and reliance on researchers' self-assurances that they are complying with requirements." The report emphasized the "need for continued vigilance over human subject research."[20] A year later, the National Bioethics Advisory Commission affirmed that "[n]o person in the United States should be enrolled in research without the twin protections of informed consent by an authorized person and independent review of the risks and benefits of the research," and in May 1999 identified as a "key concern" that "[f]ederal protections for persons serving as subjects in research do not yet extend to all Americans."[21]

Further confirmation of the seriousness of these concerns was an announcement by the National

---

[19]See Office of Inspector General, Department of Health and Human Services, *Protecting Human Research Subjects: Status of Recommendations* (April 2000). Also Jonathan Moreno *et al*., "Updating Protections for Human Subjects Involved in Research," *Journal of the Americam Medical Association* (vol. 280, no. 22, December 9, 1998): 1951-1958; R. Alto Charo, "Human Subjects Have It Worse Than Guinea Pigs," *The Chronicle of Higher Education* (June 25, 1999): A64; Lori B. Andrews, "Money Is Putting People at Risk in Biomedical Research," *The Chronicle of Higher Education* (March 10, 2000): B4-B5.

[20]*Scientific Research: Continued Vigilance Critical to Protecting Human Subjects* (Letter Report, March 8, 1996, GAO/HHS-96-72).

[21]www.bioethics.gov. Legislation introduced by Representatives Diana DeGette (Dem., Colorado), John Mica (Rep., Florida), and Henry Waxman (Dem., California) on June 8, 2000 (Hr. 4605), proposes that the Common Rule apply to all human subject research, "independent of setting and funding source."

Institutes of Health (NIH) in June 2000 that, effective October 1, 2000, it will require all investigators who submit proposals to NIH for research involving human subjects to receive training in the protection of such subjects. A national organization of research universities proposes going even further: that "all personnel" directly involved in human subject research, after appropriate training, sit for an examination "resulting in a designation (e.g., credentialing or certification)" that they may engage in such research.[22]

Perhaps more important in the long run for the government's regulation of human-subject research was the announcement by the Department of Health and Human Services (HHS) in May 2000 that it was moving the newly named Office for Human Research Protections--located in the NIH, this office has primary responsiblity within the federal government for overseeing human-subject protection regulations--to the Office of Public Health and Science within the office of the secretary of HHS. The reason for relocating the office is to "elevate its stature and effectiveness."[23]

The government's system for regulating human subject research is plainly in flux. While the precise nature of the changes cannot be foreseen, there is little doubt that the principal changes will be in the direction of expanding the scope and authority of IRBs. The impact of these changes will be felt most persistently in clinical and biomedical research, but social-science research, and quite possibly academic fields in the humanities as well, are likely to come under sharper scrutiny by IRBs. The remainder of this report summarizes and comments on the main elements of the Common Rule as they

---

[22] *Required Education in the Protection of Human Research Participants* (OD-00-039, June 5, 2000); Association of American Universities, *Report on University Protections of Human Beings Who Are the Subjects of Research* (June 28, 2000).

[23] HHS Fact Sheet, "Protecting Research Subjects" (May 23, 2000). The Common Rule itself is seen by HHS's Inspector General as a "significant barrier" to strengthening human-subject protections, for "[a]ny changes to the Rule call for the concurrence of all 17 agencies" that subscribe to it. "Legislative change may be necessary to achieve a timely implementation of many of [the Inspector General's] recommendations." *Protecting Human Research Subjects*, op. cit., 17.

pertain to social-science research, paying particular attention to the special difficulties that are presented by the application of the government's regulations to social-science research. Inevitably, some well-canvassed issues are revisited, but the likely expansion of the IRB system of review underscores the importance of scholars staying (or becoming) informed of developments that can bear directly on their research.

Part II: A Preliminary Matter: IRBs and Academic Freedom

Some researchers whose work is funded by the government have argued that the government's system of control, irrespective of whether IRBs operate well or poorly, is an improper restraint on their freedom to plan and carry out projects as they wish. They hold that IRBs are not simply unnecessary and wasteful, but, because they require them to submit their work to prior review, are at war with principles of academic freedom. This position rests on a mistaken premise, however: that a scholar has the right to be provided with federal funds to support his or her research. But no such right exists, and without it academic researchers cannot reasonably assert that they are entitled to federal funds free of restrictions meant to protect the interests of human subjects:

> If no right is violated by the imposition of a particular condition on federal research funds, then plainly no academic freedom is violated by the imposition of that condition on federal research funds. . . . No one complains if a federal agency aims at ensuring that its available research funds be expended on scientifically valuable research; and no one complains if it establishes a fair system of peer review (a form of "prior review") for assuring itself of the scientific value of a research proposal. HHS may certainly require assurance of the scientific value of a research project before funding it; we think HHS may also require assurance that the risks imposed by the research are reasonable before funding it.[24]

[24]"Regulations Governing Research on Human Subjects," *op. cit.*, 361, 362. See also John A. Robertson, "The Social Scientists' Right to Research and the IRB System," in Beauchamp *et al.*, *Ethical Issues in Social Science Research*, *op. cit.*, 362-63.

Some scholars whose research is not funded by the government but whose projects are reviewed by IRBs have also raised concerns that such reviews are a violation *per se* of academic freedom. From their perspective, the fact (as noted above) that the university, not the government, requires IRB review of their research makes a bad situation worse, for, so the argument runs, prior review of research should not be countenanced by an institution committed to principles of academic freedom. The absence of a direct financial connection between the government and the individual scholar, however, does not relieve the researcher of the professional obligation not to harm human subjects. Accordingly, a university's effort to ensure that all researchers comply with its human subject regulations does not offend academic freedom. There is the possibility, of course, that the actual rules adopted by the government or a university to protect human subjects could abridge academic freedom. This would be the case, for example, if IRBs were required to ban research deemed offensive, as some might insist should happen with respect to research on race and intelligence. This genuine threat to academic freedom could be removed by rewriting the regulations so they do not sweep unnecessarily broadly or by better educating members of IRBs. But the aim of reducing risks to human research subjects does not itself endanger academic freedom, and its abandonment would yield nothing positive for the freedom of research.

Part III: The "Common Rule"

Six issues are addressed: the Common Rule's definitions of research and of human subjects; the Rule's statements concerning the risks and benefits of research involving human subjects; the Rule's provisions regarding informed consent, and research that is exempt from this requirement; research that is subject to an expedited review procedure; the composition of IRBs; and, lastly, the appeal of IRB

decisions.

1. What Is Research? What Is a Human Subject?

According to the Common Rule, research is "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."[25] Very little "systematic investigation" in the social sciences, and perhaps none in clinical and biomedical specialties, falls outside this definition. While the Rule does not define "generalizable knowledge," and therefore leaves that task to each IRB, the work of most social scientists aims at furthering such knowledge. But the exceptions are not trivial. At the University of North Carolina at Chapel Hill, professors and students in the School of Journalism and Mass Communication who gather information for newspaper articles were concerned that IRB review of such activity would violate their rights of freedom of the press under the First Amendment. The faculty, the students, and the IRB agreed that newspaper stories do not contribute to generalizable knowledge, and therefore are not subject to IRB review. At Stanford University, the research projects of honors or graduate students that "employ systematic data collection with the intent to contribute to generalizable knowledge" must be reviewed by the IRB; by contrast, research seminars that provide research training for students but do not contribute to generalizable knowledge are not subject to IRB review.[26]

Like the definition of research, the definition of "human subject" is cast in broad language: "a

---

[25] 46 *CFR* 46.102(d).

[26] University of North Carolina at Chapel Hill, *Academic Affairs-IRB Guidelines for the School of Journalism and Mass Communication* (2000); http://www.stanford.edu/dept/dor/nonmedhs/.

living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.'[27] The terms "intervention," "interaction," and "private information" are also defined:

> *Intervention* includes both physical procedures by which data are gathered . . . and manipulations of the subject or the subject's environment that are performed for research purposes. *Interaction* includes communication or interpersonal contact between investigator and subject. *Private communication* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public.[28]

Obviously there is social-science research that does not focus on "a living individual," and thus lies beyond the reach of the Common Rule. But should a researcher who interviews the living to learn about the dead be concerned that such activities are within the Rule's purview? Perhaps, especially if the researcher is seeking, in the words of the Common Rule, either "data through intervention or interaction with the individual, or (2) identifiable private information." The Rule is clear, however, that "final judgment" about whether a particular activity is covered by the policy rests with the government, and thus the IRB, and not with the researcher.[29]

The Rule is also clear about the categories of research--six in all--that are explicitly exempt from the policy, notwithstanding the involvement of human subjects and funding by the government. The categories cover a broad range of social-science research, specifically: (1) research in education settings on instructional techniques, curricula, or classroom-management methods; (2) research involving the use

---

[27] 46 *CFR* 46.102(f).

[28] *Ibid.*

[29] 46 *CFR* 46.101(c).

of educational tests, survey procedures, interview procedures, or observation of public behavior, unless the subject can be identified and disclosure of the subject's responses could put the individual at risk of criminal or civil liability or could damage the subject's financial standing, employability, or reputation; (3) research involving elected or appointed officials or candidates for public office; (4) studies using existing data, documents, or records, as long as these resources are publicly available or the human subject cannot be identified; (5) studies of public benefit or service programs; and (6) research focusing on consumer consumption of food and the taste and quality of food.

Common to these kinds of research is that they pose little or no risk of physically or mentally harming human subjects. Whether, in a particular instance, the risk is more than minimal is for an IRB to decide.[30] The IRB can, and usually does, require that the researcher submit documentation to verify that the project is indeed exempt from review, and the quantity submitted can rival in bulk what is required for research that is not exempt. At the University of Nevada, Reno, the "Statement of Exemption from Review by [the] Human Subjects Committee" asks the researcher to send along with the completed statement the "informed consent form and instruments, i.e., questionnaire, test, interview transcripts, stimulus material, letters of permission from sites of performance, etc."

It is not surprising that an IRB may want to review documents to ensure that research involving human subjects is properly exempt from the Common Rule. Nor is it surprising to learn that IRBs often retain for review research that is eligible for exemption.[31] It would be equally unsurprising to learn that

---

[30]According to the Common Rule, minimal risk "means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." *Ibid*. 46.102.h.i.

[31]"In the present study, chairs [of IRBs] reported that about one-third of protocols eligible for exemption were actually exempted from review." *Evaluation of NIH*, VII-3.

members of an IRB who have doubts about whether a research project should be exempt favor classifying the research as not exempt in order to avoid appearing cavalier about risks to human subjects. No one is likely to get into trouble for insisting that a research proposal is not exempt.

The inclination of an IRB to do more rather than less in reviewing research is of a piece with a university's decision, referred to earlier in this report, to extend the IRB's authority to human-subject research not funded by the government. That a university would take this step can be explained in several ways.There is, to begin with, the language of the Common Rule. The definitions of "research" and of "human subject" are not narrow, and their broad sweep are encouragements to universities, if they are so minded, to assert their authority over all research that involves human subjects. Perhaps more to the point, the Rule encourages universities to be so minded, for they are required to provide an "assurance" to the government that "at a minimum" includes:

> A statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution, *regardless of whether the research is subject to Federal regulation*.[32]

The assurance attests to a university's willingness to comply with the policy. Without it, no governmental department or agency that subscribes to the policy can fund research at a university. While the Rule does not prescribe the content of a statement of principles, a university is plainly under considerable pressure from the government to apply its procedures to all human-subject research.

There is also the pressure of possible litigation. Consider the following: a privately funded research project is carried out at a university, one of the human subjects claims to have been harmed by the research, and the subject sues the university. Consider further that the university's IRB does not

[32] 46 *CFR* 46.103 (b)(1), emphasis added.

review research that is not funded by the government. The litigant will almost certainly argue that the university's failure to review privately funded research while it reviews government-funded research is proof that it acted unreasonably. Conversely, had the university's IRB approved the research, the university will cite that fact as evidence of its reasonableness in permitting the research to go forward.[33] Whatever the merits of these arguments, the university's legally prudent course of action, so the lawyers will advise, is for its policy to apply to all research on human subjects, irrespective of the source of funding. An aversion to legal risks may also help explain the actual decision of IRBs, to the extent that they seek to protect the institution (and perhaps themselves as well) from lawsuits that allege mistreatment of human research subjects.

Lastly, no university is likely to want to explain to either the government or the public why its commitment to avoid harming the human subjects of research is limited by the source of funding for the research. This prospect is even less attractive as IRBs expand their authority in response to concerns that the government must do more to protect human research subjects.

2. *The Risks and Benefits of Research*

In deciding whether or not to approve research covered by the Common Rule, an IRB must first determine that the "risks to subjects are minimized" and that the research procedures "do not unnecessarily expose subjects to risk.'[34] Risks that are minimized--not, it should be noted, risks that are

---

[33]"Regulations Governing Research on Human Subjects: Academic Freedom and the Institutional Review Board," 368. Richard Tropp argues that civil-rights legal precedents, which require the extension of civil rights statutes to all parts of a university campus, beyond the departments or projects that actually receive federal dollars, apply "exactly to the issues of protection of subjects in nonfederally funded research. The precedent requires that IRBs assert their authority over all research on a campus . . . which receives any federal dollars at all." "A Regulatory Perspective on Social Science Research," in Beauchamp *et al*., *Ethical Issues in Social Science Research*, 394-95.

[34]46 *CFR* 46.111(1).

minimal--may still pose dangers to the subjects. This is true of a great deal of clinical and biomedical research and of some social-science research. The IRB's next task is to determine whether the risks "are reasonable in relation to anticipated benefits, and the importance of the knowledge that may reasonably be expected to result." The Common Rule continues:

> In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.[35]

The fact that IRBs are barred from reaching judgments about the "possible long-range effects of applying knowledge gained in the research" is an unalloyed gain for the social sciences. If IRBs were to venture into this kind of prediction, they would almost certainly be drawn into political controversies to the detriment of the research and of their own credibility. Social-science research can easily become entangled with public policy debates, as suggested by even the briefest (arbitrary) listing of social-science research topics: homicide rates in large cities, religious beliefs of federal judges, performance of the armed forces during the Gulf War, and the role of folk doctors in immigrant communities. The results of each of these studies could influence public policy, but, as has been remarked, local IRBs are not the proper forum for a debate about the policy implications of research and, in any event, the debate should occur after, not before, the research takes place.[36]

The risk-benefit analysis that IRBs are required to carry out is not free of problems for the social sciences, however. A request by an IRB for a description of the risks and benefits of a research

---

[35] 46 *CFR* 46.111(2).

[36] Gray, "The Regulatory Context of Social and Behavioral Research," op. cit., 348.

project assumes that the research lends itself to this kind of analysis. In the social sciences, this can be a questionable assumption:

> Biomedical research affects the "biological person"; harms and benefits are tangible, physical, and, most frequently, measurable. The harms and benefits of social research, on the other hand, are psychological or social and rarely measurable While the level of risks in social and behavioral research is ordinarily low, it is often quite difficult to show that basic research in these fields produces "benefit," unless one considers any increment of knowledge to be a benefit. . . . Most people are willing to accept the possibility that basic biomedical research will eventually prove beneficial, and they can perceive the researcher's motivations in such terms. However, the value of much basic social and behavioral research is not as intuitively obvious. Further, many of the problems for study are undoubtedly selected because of the personal values of the researcher or because the problem seem "interesting," not out of a belief that the research will lead to some utilitarian benefit.[37]

This is not to suggest that risk-benefit analysis is inapplicable to social-science research, but rather to emphasize a simple proposition: that different kinds of risks and benefits are associated with different kinds of research. The research of an oral historian does not require the kind of review an IRB will do concerning research by an oncologist. And while it may not be feasible, in administering the Common Rule, to distinguish all the shadings that lie between oral history and oncology, fairness requires some distinctions to be made. The difficulty, of course, with such an admonition is not in making it acceptable, but in making it workable. How does one ensure that IRB judgments about risks and benefits are nuanced? The quality of IRB decisions depends ultimately on the experience and good sense of members of IRBs. The way to avoid rigidity and thus unfairness in IRB decisions is to have skilled IRB members (discussed below under the "Composition of IRBs"), and then to subject their decisions to possible appeals (also below, "An Opportunity to Appeal an IRB Decision").

---

[37]Gray, "The Regulatory Context of Social and Behavioral Research," op. cit., 347.

But assume for the moment that an IRB has determined that the risks of a research project are reasonable in relation to anticipated benefits. According to the Common Rule, the IRB has one more task: it must also determine that the risks are reasonable in relation "to the importance of the knowledge that may reasonably be expected to result." This is another problem concerning the application of risk-benefit analysis to social-science research, for the IRB's second assignment is a baffling one. As a practical matter, it seems implausible that an IRB would find that the risks of a research project are reasonable in relation to its anticipated benefits, but not in relation to the importance of the knowledge that might result. A more likely scenario (for social-science research as well as for clinical and biomedical research) is that an IRB's judgment about the benefits of the research becomes in effect a judgment about the importance of the research: if the research is beneficial, the knowledge that may result is important. This much seems straightforward, albeit technically inconsistent with the Common Rule.

For social-science research, however, a serious issue can arise if an IRB comes to focus on the importance of research because, for reasons suggested above, it cannot get a fix on the putative benefits of the research. The trouble lies in the selection and emphasis that inevitably occurs in judgments that are made about the importance of research, especially when the research is proposed rather than completed. Will it yield a lasting scholarship? Does it proceed along routine lines? Is it provocative, dull, or somewhere in between? Answering these and a multitude of additionally familiar questions can be difficult for members of an academic department, who are usually better qualified than anybody else to judge what is important in their fields. For members of an IRB who are not familiar with social-science research, however, the task can be daunting. Or, paradoxically, it can be easy, if they indiscriminately

apply standards of research drawn from clinical or biomedical specialties to the social sciences, much to the dismay of social scientists.

There is another concern. The mere existence of the requirement that IRBs evaluate the risks of the research in relationship to its importance can have an inhibiting effect on the work of scholars. Inhibitions on research can have numerous causes, and academic researchers take for granted the pressures that derive from having their work reviewed by colleagues. But the pressures of IRB reviews are different, for behind them is the weight of the government and the specter of the official control of opinion. This is not to say that control of opinion is the purpose of IRB reviews; manifestly it is not. But an IRB review that seeks to evaluate the importance of research can lean in that direction if only because judgments about the importance of research are highly speculative. From the perspective of the scholar with so much at stake in obtaining IRB approval, the uncertainty about whether any particular research project will be considered important in relation to its risks, and the vagueness of such an inquiry, may dampen enthusiasm for challenging traditional habits of thinking, or testing new theories, or criticizing social and political institutions. Why chance an IRB's displeasure when a more cautious approach is likely, so the scholar might plausibly reason, to secure uncontroversial approval?

Evidence that IRB reviews may have had such repressive effects is anecdotal, gleaned from the surveys of several professional organizations described earlier in this report.[38] But a description of the challenges of applying IRB reviews to social science research would be seriously incomplete if it ignored the danger to freedom of research--if only through self-censorship-- implicit in the requirement that IRBs evaluate the importance of research.

---

[38]See n. 11.

3. *Informed Consent*

Perhaps the single most important element in the IRB review process is the requirement that the researcher obtain the informed consent of the human being who is a subject of the research. In the words of the Common Rule: "[N]o investigator may involve a human being as a subject in research covered by this policy, unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative."[39] One measure of the importance of this requirement is that researchers who have been required by an IRB to revise their proposals report that the most common reason for change is to modify consent forms.[40]

The requirement is rooted in the principle that "individuals should be treated as autonomous agents and . . . that persons with diminished autonomy are entitled to protection." More specifically, "respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided when adequate standards for informed consent are satisfied."[41] The standards or elements of informed consent are stated in the Common Rule as types of information that are to be provided to each research subject:

> 1. A statement that the study involves research, an explanation of the purposes of the research, and expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
>
> 2. A description of any reasonably foreseeable risks or discomforts to the subject;

---

[39] 46 *CFR* 46.116

[40] *Evaluation of NIH*, V-12.

[41] *Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research* (Washington, D.C.: Department of Health, Education, and Welfare, 1979). This seminal document, known as *The Belmont Report*, is reprinted in Jeremy Sugarman, Anna C. Mastroianni, Jeffrey P. Kahn, eds., *Ethics of Research with Human Subjects: Selected Policies and Resources* (Fredrick, Maryland: University Publishing Group, 1998): 19-30.

3. A description of any benefits to the subject or to others which may reasonably be expected from the research;

4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

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

7. 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; and

8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled.[42]

It is worth emphasizing that not all of these criteria can apply to all research projects, particularly when the projects involve no risk of physical or mental harm to the research subjects. But controversies have persisted in the social sciences about the nature and possibility of informed consent. For example, concern has been expressed that explaining the purposes or the benefits of the research may run the risk of skewing the research results, because the subject can change his or her behavior based on the new knowledge. If, for example, subjects are told that a principal purpose of the research is to observe unobtrusively their conduct under stressful conditions, their behavior is not likely to be spontaneous. What can a researcher tell a subject about either the purpose or the benefits of the research if deceiving

[42] 46 *CFR* 46.116.a.

the subject is necessary to carry out the research? If the researcher is studying illegal or stigmatized behavior, obtaining consent may be infeasible or pose a greater risk to the subject than the research itself. How is "legally effective informed consent" to be obtained from human subjects in non-literate societies, or who consider the act of signing documents as antithetical to their religious beliefs?[43]

The Common Rule addresses these kinds of concerns in two ways. First, an IRB can approve a consent procedure that does not include all the elements of informed consent, or that alters some or all of them, or, in the alternative, waives the requirement entirely. The IRB can take these steps if it establishes that the risks to the subject are minimal, that the waiver will not "adversely affect the rights and welfare of the subject," and that without the waiver the research could not be "practicably carried out."[44] Second, an IRB that calls upon the researcher to obtain the subject's consent can waive the requirement that the consent be in writing under either one of two conditions. The first requires that the only record linking the subject and the research is the consent document, and that the principal risk to the subject would be the harm resulting from a breach of confidentiality. A striking feature of this condition is that the subjects are to be asked whether they want documentation linking them to the research, and the subjects' "wishes will govern."[45]

The second condition requires that the research pose no more than a minimal risk of harm to the

---

[43]See the essays in Beauchamp *et al*., *Ethical Issues in Social Science Research*, *op. cit*., under "Informed Consent and Deception." See also Marian W. Fischman, "Informed Consent" in Bruce D. Sales and Susan Folkman, eds., *Ethics in Research With Human Participants* (Washington, DC: American Psychological Association, 2000): 35-48. For issues of informed consent in the setting of internet research see Mark S. Frankel and Sanyin Siang, *Ethical and Legal Aspects of Human Subjects Research On the Internet* (Washington, D.C.: American Association for the Advancement of Science, 1999): 6-10.

[44]46 *CFR* 46.116.d.

[45]46 *CFR* 46.117.c.1.

subject, and "involves no procedures for which written consent is normally required outside of the research context." The last point refers to the fact that one does not usually ask persons for written consent in order to question them or (as another example) to observe them on a street corner, and thus it is not necessary to obtain written consent to do likewise for a research project.[46]

For decades, scholars at the University of Michigan have been in the forefront of large-scale survey research. A large proportion of their research poses minimal risk to the subjects of that research and qualifies for expedited review.[47] In such cases, the campus IRB frequently waives the requirement for written consent and considers a returned questionaire as evidence of implied consent. The IRB also reviews explanatory materials accompanying a written questionnaire or the script to be used in a telephone interview. IRB reviews of large-scale survey research at other universities may proceed along the same lines, but there is no way to even guess at the number of social-science researchers (or, indeed, the number of researchers in any academic field) who request waivers of the consent requirements or of the number of IRBs that grant them. Of course, gross figures, even though significant, would not measure the difficulties researchers can encounter in seeking waivers from their IRBs. One difficulty, alluded to earlier, is the inclination of IRBs not to appear slack in protecting human research subjects. Another are the presumptions implicit in the Common Rule: that a subject's written consent will need to be obtained, and that the burden rests with the researcher to show why the consent requirements should be altered or waived. At Stanford University, the presumptions are made explicit: "Written, signed consent should always be sought unless there are compelling reasons to seek a partial

---

[46]This follows Gray, "The Regulatory Context of Social and Behavioral Research," op. cit., 347. Also 46 *CFR* 46.117.c.2.

[47]On expedited reviews, see below.

or full waiver of consent." And: "Justification must be provided for any modfication of full consent procedures."[48]

The obstacles that a researcher faces in persuading an IRB to alter or waive consent requirements help to explain why controversies about informed consent in the social sciences have not abated. Consider this description of a scholar studying curanderos, native healers who provide Hispanic communities with medical advice, prescriptions, and treatments:

> When [the researcher reported her interests] to the administrators of her program and they, in turn, to the IRB, she was instructed she must secure from the curanderos signed papers of informed consent. To her credit, this action was one she would not do. The curanderos have very good reasons to keep their identities concealed from figures of authority. Some are illegal immigrants. Depending upon local law, they could be charged with practicing medicine without a license. Most are illiterate. Most have a poor command of the English language, [and a] limited understanding of what might be implied in signing any sort of legal form.
>
> [The researcher] spent many months in anxious negotiations with her university administration. Finally she was ingenious enough to gain the agreement of a few administrators to the following: That at the start of a tape-recorded interview, the curandero or curandera would confer a blessing upon [the] research activities rather than identifying himself or herself and, thereby, stating consent.
>
> But, unhappily, [the researcher] had to waste precious time scheduled for research in hassling with administrators about an investigation basic to the institution's mission. By the time the research with curanderos received some partial approval, a major portion of the funds budgeted for transcription and translation were no longer available. A further consequence was that her graduate students were frustrated in their apprenticeships.[49]

The reference to graduate students deserves emphasis. When they (and undergraduates, too) see the kinds of difficulties that professors encounter with IRBs, they might decide, if they are to finish their degrees in a timely way, to avoid research that is subject to the Common Rule. That this may occur

---

[48]http://www.stanford.edu/dept/dor/nonmedhs/.

[49]Testimony of Professor Murray L. Wax before the National Bioethics Advisory Commission, *op. cit.*.

is borne out by information gathered informally by several professional organizations from their members in the spring 2000.[50] From this group of respondents (approximately two hundred professors) came reports of students turning away from research that would have had to be submitted to the campus IRB, and even of some professors encouraging their students to do so.

In the same survey, scholars report that they have sought to avoid IRB review, not only because of impatience with the procedure but, more important, because of a disinclination to have their research proposals reviewed by individuals unfamiliar with their field of study. Scholars are thus put in the position of circumventing a legal requirement because it seems to them unfair, irrelevant, or both.

In summary, then, IRBs may be prone to implement the Common Rule with too much rigor and too little consideration of the diverse nature of academic research. To the extent that this happens, IRBs can needlessly impede social-science research.

4. *Expedited Review*.

Through an expedited review procedure, the Common Rule offers a way to reduce impediments. The procedure is simple. The review of the research is carried out by either the chair of the IRB or another member (or members) of the IRB designated by the chair. In other words, a review is expedited not because of a different procedure--the Common Rule specifies that "standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review"--but because fewer people are doing it. The IRB members who are responsible for conducting an expedited review can approve the research, but, apparently in recognition of the

[50]See n. 11 above.

significance to an investigator of an adverse decision, only a full IRB can disapprove the research.[51]

For research to be eligible for expedited review, it must pose no more than a minimal risk to the human subject(s) and fit into one of nine research categories. Of the nine categories, two are directly relevant to social-science research:

> (6) Collection of data from voice, video, digital, or image recordings made for research purposes.
>
> (7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.[52]

It is worth noting that these research categories were announced in 1998, and that they are different from the categories in place before then. Under the earlier categories, "activities" eligible for expedited review included "research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects' behavior and the research will not involve stress to subjects."[53] The shift in wording represents a broadening of the categories: the earlier, narrower categories made it more difficult for social scientists to qualify for expedited review, and perhaps placed a heavier burden on the IRB--because such a review was available in only relatively limited circumstances--that wanted to proceed with an expedited evaluation. Here, then, is an instance, within the framework of expedited review, of the government's revising its rules to the advantage of researchers in the social sciences.

---

[51] 46 *CFR* 46.110.

[52] "Categories of Research That May Be Reviewed . . . through an Expedited Review Procedure," *op. cit.*

[53] 46 FR 8392 (January 26, 1981).

A distinctive characteristic of expedited review should be prompt approval of research proposals, unless, of course, disapproval is in prospect. A maximum of two weeks seems reasonable, especially since IRBs are much less likely to ask a researcher to modify a proposal under the expedited procedure than with a review by a full board.[54] Will this continue to be true as the workloads of IRBs expand, as is almost certain to occur, in response to concerns that they must be more vigilant in protecting human subjects? There is no way to know. But when public concerns with IRBs run high, the commonplace--reasonably efficient handling of expedited reviews--may become atypical. Still, it is reasonable to assume that IRBs which have learned to facilitate expedited reviews can adapt themselves to do the same in a changing political environment. As for investigators who believe that their research meets the criteria for expedited review, they must take the initiative to persuade IRBs to review their proposals promptly. Researchers have no choice but to proceed on the assumption that an IRB, fully and accurately informed, will not delay. The assumption may prove false, but the burden is necessarily on researchers to make their own case.

5. *The Composition of IRBs*.

Who serves on IRBs is no small matter to either researchers or the government, and the latter has left few stones unquarried in shaping the composition of the boards:

> Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of its members, including consideration of race, gender, and cultural backgrounds, and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of

[54]The *Evalution of NIH*, IV-19, found that eighty-four percent of expedited reviews were completed in eight to thirty days. For data on the frequency of IRB requests for changes in research proposals, see *ibid*., V-12.

> human subjects. In addition to possessing professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas.

Nor is this all. No IRB "may consist entirely of members of one profession," every "nondiscriminatory effort" will be made to ensure that no IRB "consists entirely of men or entirely of women," and each IRB will have at least one member "whose primary concerns are in nonscientific areas."[65] Embedded in desiderata such as sensitivity to community attitudes and regard for institutional commitments are notions of accountability which, if they were given serious weight by IRBs, might pose a serious threat to academic freedom and the independence of academic researchers. This important but intangible concern must remain speculative. For social scientists, a more immediate issue is their representation on IRBs.

As would be expected, the composition of IRBs varies with the type and volume of the research proposals they review. At the nation's largest research universities, it is not uncommon to find several IRBs serving a single institution. For example, the IRB at the University of Minnesota (approximately 2,500 full-time faculty members) is divided into six panels: four review research in the health and biological sciences, one reviews research in the social sciences, and the sixth addresses policy issues and provides guidance to the other five panels. By contrast, the single IRB at St. Lawrence University (approximately 150 full-time faculty members) consists of four faculty members, including a psychologist and a sociologist, and two individuals from outside the institution.

Social scientists are not underrepresented on the IRBs at these two institutions. But between the

largest research universities and very much smaller campuses there is a middle-range of institutions (from about 500 faculty members to upwards of 1,500) where typically one IRB with few social scientists (sometimes only one) oversees compliance with the Common Rule. These IRBs can be fairly large; the IRB at the University of Alabama at Birmingham has thirty-six members, and of this number one is a psychologist. A brief explanation for the small number of social scientists is the fact that clinical and biomedical research is still the dominant (but not exclusive) focus for IRBs at these institutions. For members of an IRB who spend a good deal of their time reviewing clinical and biomedical research, the time they give to social-science research may seem relatively minor. But it is not minor to the social scientists who must go through the review.

As quoted above, the Common Rule requires that persons who serve on IRBs will have the "professional competence necessary to review *specific* research activities," and will be "knowledgeable" about "standards of professional conduct and practice."[56] In practical terms, what does this mean for the social sciences? One can argue that researchers in the clinical or biomedical fields cannot meet these criteria at all, for, apart from the rare polymath, they do not have the professional training or experience to evaluate "specific research activities" in the social sciences. Of course, the same argument applies in equal measure to social scientists reviewing clinical or biomedical research.

Because of their expertise, and because IRBs are likely to be reviewing more social- science research than they have in the past, social scientists should, in larger numbers than is currently typical

---

[55]46 *CFR* 46.107.

[56]Emphasis added.

among middle-range universities, be regular voting members of IRBs.[57] How many are needed? The Common Rule does not give an answer, and common sense suggests that it is bootless to look for a precise formula or quota. Still, an impression of magnitude may be helpful. One is too few. The lone social scientist must not only be familiar with standards and techniques of research in the social sciences at some distance from his or her own--to the political scientist, for example, social psychology may be *terra incognita*--but must also contend with the homogenizing pressures within the IRB for its members to reach the same judgments in accord with the same values. A minimum of three social scientists seems a reasonable guess.With this number, there is a better chance that one or more of the social scientists on the IRB will be familiar with most of the major research techniques in the social sciences involving human subjects. There is also a better chance for a vigorous exchange of ideas about social-science research to take place among all the members of the IRB to their mutual benefit.

Another approach is for a middle-range institution to establish a separate IRB to focus solely on research in the social sciences. At some institutions, these IRBs might have relatively few projects to evaluate. But whether an IRB's agenda is crowded or not, the aim is to ensure that social scientists have an opportunity to play an effective role on IRBs. We cannot make the best of IRBs until this is done.

6. *An Opportunity to Appeal an IRB Decision*

A scholar whose research is subject to evaluation by an IRB is entitled to a review that is full and fair. Ideally, members of the IRB assemble all the information required for a responsible decision, weigh the several considerations mandated by the Common Rule for determining whether the research

[57]The Common Rule anticipates the problem of insufficient expertise. It states that an IRB "may, at its discretion, invite individuals with competence in special areas to assist in review of issues which require expertise beyond or in addition to that available on the IRB." This is a useful approach to the problem, but a limited one, for the Rule adds: "These individuals may not vote with the IRB." 46 *CFR* 46.107(f).

should be approved, and reach a conclusion on the basis of their best informed judgment. The ideal is not always realized in practice, however, and the researcher who suffers the sting of an adverse IRB decision is unlikely to be mollified by assurances that the board members did their best. What is needed is for some other body to consider a researcher's complaint that the decision of the IRB was not full or fair.

In 1981, the government acknowledged this need. It did not recommend a mechanism for appeal from IRB decisions, for the IRB is the "final authority at the institution regarding the ethical acceptability of proposed research involving human subjects." At the same time, it did not "rule out the possibility of an institution's establishing an appeals process in order to provide a second review of research activities that were disapproved by an IRB." It insists, however, that the appellate body "meet all the requirements" of the Common Rule, "including those specifying membership requirements."[58] In other words, the appellate body is another IRB, which, under the government's regulations, is the only body that can approve research which has been disapproved in an initial IRB review.[59]

There is little likelihood that colleges and universities will establish IRBs solely for the purpose of considering the appeals of researchers.The additional administrative burdens of doing so are a serious deterrent, while researchers understandably would question whether a second IRB review under the same standards as the first would yield a fairer result. The challenge is to have a procedure for appeal

---

[58]Cited in Gray, "The Regulatory Context of Social and Behavioral Research," 354-55, note 28.

[59]The 1991 Common Rule states that research approved by an IRB may be subject to further review for approval or disapproval by officials of the institution, but the officials "may not approve the research if it has not been approved by an IRB." 46 *CFR* 46.112. A researcher whose project is approved by an IRB is unlikely, to say the least, to seek further review, but not so a third party, for example, a member of the community at large or even a senior administrator at the university, who believes that the IRB has erred. It is worth emphasizing that the Common Rule does not require disapproval of IRB-approved research by another IRB. Action by "officials of the institution" apparently suffices.

that lies outside the IRB system but does not breach the government's requirement that only an IRB-type body can overrule an IRB's disapproval of research.

By what process can this be achieved? One approach is for the appeal body not to substitute its own judgment for that of the members of the IRB on the merits of whether the research should be approved. Instead, the appeal body would focus on questions such as the following: was all available information bearing on the proposed research sought out and considered? Was there adequate deliberation by the IRB of the information in light of relevant professional standards? Were irrelevant standards excluded from consideration? If the appeal body answers these kinds of questions in the negative, its appropriate response is to recommend to the IRB that it assess the merits of the research again, this time remedying the inadequacies of its prior consideration.

From the perspective of the institution, an argument against this approach is that the administrative machinery (and thus the administrative burden) necessary to implement it may come to resemble an IRB in all but name. From the perspective of the researcher, an appeal body that cannot address the merits of the proposed research, and can only recommend a course of action to the IRB, may seem ineffectual and a waste of time. The advantage of this approach is that it is not clouded by the problem of overturning an IRB decision, and focuses the attention of the institution, the IRB, and the researcher on the key issue of whether the right professional standards have been applied in the right way to the particular academic field of study.

No doubt there are other approaches to IRB decisions and appeal. Whatever approach is pursued, a time when the government's regulatory structure for protecting human research subjects is in the process of important change is perhaps better than most for a serious effort to improve the

functioning of campus IRBs. And one promising avenue toward productive reconstruction are workable mechanisms for the appeal of IRB decisions. .

Part IV: Recommendations

Suggestions for the improvement of IRB practices and recommendations, explicit as well as implicit, are included in various parts of this report. What follows is a review of the more important recommendations.

As described above, social scientists have had some success in persuading the government to give fuller recognition to the kind of research they pursue and how it differs from clinical and biomedical research. This was notably the case in 1998 with the broadening of the research catgeories that can be reviewed by IRBs under an expedited procedure. Still, expedited review is of little value to social scientists if the members of IRBs, in the words of the Common Rule, lack the "professional competence necessary to review [their] specific research activities." Although this unsatisfactory situation may slowly improve as IRBs review more social-science research, there is a need now to increase the number of social scientists serving on IRBs. The need is pressing because there is good reason to believe that, even as this report was being prepared, more social-science research was coming under more exacting IRB review.

Better representation of social scientists on IRBs can also help make their decisions more credible. So, too, can the opportunity for appeal. An appeal of the decision of an effective IRB should be rare, but the institution and the IRB should be prepared for it, so that both institutional integrity and the rights of the researcher may be preserved.

The Common Rule describes the type of research that is exempt from the government's

regulations and the type of research that an IRB can review under an expedited procedure. A responsible IRB will give serious attention to applying these standards for exemption and expedited review to the particular needs of social-science research. It will also avoid unnecessary delays in decisions.

The complicated tasks performed by IRBs, this report has implied, produce an inescapable interdependence among university administrators, members of IRBs, scholars, and students, but plainly the relationship calls for better communication among these components. What can be done? One course of action is for administrators to help social scientists on their campus understand and deal with issues of research ethics that arise in IRB reviews--through campus-based seminars, symposia, and the like to which would be invited past and current IRB members, social science researchers who have gone through an IRB review, and researchers likely to face one.

IRB members can be helpful (perhaps with staff assistance) by preparing and distributing synopses of the research proposals they have reviewed with a brief description of their disposition. Simply compiling a list of research proposals by their titles (and updating it annually) would usefully give others a sense of the scope of IRB reviews.

Social scientists should continue to speak out against what they see as threats to freedom of research. They should also share their experiences with others on the campus: with administrators, who may profit from a close-at-hand view of how the campus IRB actually operates as seen by those most immediately affected by its work; with current members of the IRB, so that the may have a stronger awareness of the challenge of applying the Common Rule to social-science research; and with other social scientists and students, so that they may anticipate and address issues likely to be of concern to

the IRB.

Lastly, IRB members could discuss with academic departments the possibility of blanket exemptions for certain types of research (for example, survey research or oral history research), and the IRB's delegating to the department responsibility for an initial review of research that does not pose a threat of physical or mental harm to human subjects. Departments could also maintain a file of research projects that have undergone IRB review to be consulted by department members and students as the need arises.

Over the past three decades, growth has been the most obvious characteristic of the government's system for protecting human research subjects: growth in the number of IRBs and growth in the number of research projects reviewed by them. The problems of complexity associated with this growth are themselves enormously complex, and the complexity has been compounded by the fact that the standards and techniques of academic research involving human subjects are not static. In retrospect, the problems experienced by researchers in the social sciences (and the humanities, too) in dealing with IRBs may have been predictable and inevitable, but they can be addressed. Recognition by IRBs of these problems is perhaps the first important step in their grappling substantively with them. More concretely, IRBs need to give thoughtful consideration--this report has pointed to ways to achieve this goal--to the practices and ethics of social-science research when reviewing projects proposed by social scientists. To the extent that this is done, social scientists will treat IRB decisions with the respect they deserve; to the extent that it is absent, their confidence in IRB decisions will erode.