Having an Institutional Review Board (IRB) review and monitor the use of human subjects is now fundamental to ethical research. Yet social scientists appear increasingly frustrated with the process. This article aims to assist evaluators struggling to understand and work with IRBs. The author theorizes why IRBs frustrate and insists there is only one remedy: We must accept the legitimacy of IRB review and (a) learn more about IRB regulations, imperatives, and the new pressures on them; and (b) educate IRBs about social scientific methodologies and empirically demonstrable risks. A research agenda and tips are offered.

RISKS AND WRONGS IN SOCIAL SCIENCE RESEARCH

An Evaluator's Guide to the IRB

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An Institutional Review Board (IRB) is a committee of five or more diverse individuals who review research protocols and monitor ongoing studies to ensure the protection of human research subjects. IRBs are typically local and therefore presumed to understand the concerns of the community where research is conducted. Although almost always part of a research organization, to be legitimate an IRB must operate independently of its authority structure. Although federal regulations must be adhered to and IRBs have the authority to disapprove research, modern IRBs aim to work with, educate, and learn from researchers on how best to protect human research subjects.

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The horrific experiments conducted by otherwise revered Nazi doctors forced the courts, the medical community, and the public to consider the protection of human research subjects (Annas and Grodin 1992). But the effect of the trial, by which seven were executed, and the resultant Nuremberg Code was imperceptible in the United States (Moreno 1997; Rothman 1994). Americans believed that its physician-researchers acted in accordance with their Hippocratic Oath and that "voluntary consent" was unnecessary in a society with a long and untarnished history of medical research (Moreno 1997). The belief was defective.

The Tuskegee study, which began in the 1930s and lasted until 1972, withheld treatment and information from a group of 399 poor Black men suffering syphilis infections (Jones 1993; Peckman 2001). subjects were unaware that they were being denied treatment and did not give informed consent. Other such examples include experiments to develop a hepatitis vaccine conducted on institutionalized children and a study in which hospitalized elderly Jewish patients were unknowingly injected with cancer cells (Kahn and Mastroianni 2001). That he culled his list of ethical violations from papers published by investigators at prestigious institutions made Beecher's (1966) landmark effort to document research risks all the more disturbing. Social and behavioral scientists were not beyond reproach. Among others, Milgram's (1974) obedience experiments and Humphreys's (1975) "tea-room" observations are reminders of the potential risks posed by deceptive social and behavioral research (Moreno 2001; Pattullo 1984).[1]

By the late 1960s, it was abundantly clear that regulatory oversight of medical research was necessary (Curran 1969).[2] New regulations meant that to receive federal funds, research organizations had to set up committees to ensure the protection of human research subjects (Pattullo 1984). IRBs emerged and today play a prominent role in all research. It is unclear exactly how many active IRBs are now in existence; speculation is that the number exceeds 4,000 (Amdur and Bankert 2002a).

Despite the irrational fears expressed 20 years ago (de Sola Pool 1979, 1980; Seiler and Murtha 1980), IRBs have not halted research and most social scientists appear undisturbed by the oversight. This seems due to the fact that most everyone discounted the risks associated with social scientific research. Yet in just the past few years, IRBs have increased their scrutiny of social scientific protocols and all indications suggest even more scrutiny is imminent. Such heightened oversight can create great difficulties for IRBs who must balance less familiar risks and benefits, carefully review a mountain of applications, and assess such protocols within a predominantly biomedical framework. But this is not my focus here.[3] Of interest are social scientific program evaluators, many of whom seem extraordinarily sympathetic

to IRB oversight but who also appear increasingly frustrated, annoyed, and upset by IRB decisions, inconsistencies, delays, and misunderstandings (Hessler, Galliher, and Reynolds 1983; Murray 1998; Niemonen 2000; Ross et al. 2000; Shea 2000; Timmermans 1995; Warren and Staples 1989). Because no research may be conducted without IRB approval, it is understandable that strong feelings obtain.

Although many distinguished evaluators discuss ethical research and professional behavior and there are clear guidelines, it is remarkable how little attention has been paid to IRB issues.[4] For example, neither Rossi, Freeman, and Lipsey (1999) nor Weiss (1998) discussed IRB requirements. Dillman (2000) merely noted that IRBs are part of the survey process. There are many excellent book-length discussions about ethical social research (Beauchamp and Childress 1994; Beauschamp et al. 1982; Diener and Crandall 1978; Stanley and Guido 1996), but they devote little attention to contemporary and practical aspects of the IRB.[5]

This journal has published several articles about ethics: One evaluated the ethics of whistle-blowing (Wenger et al. 1999), a few addressed the ethics of evaluators themselves (Brown and Newman 1992; Morris and Cohn 1993; Sheinfeld and Laord 1981), and one addressed ethical issues with respect to HIV vaccines (Marimer 1990). Several contributions addressed the effects of active versus passive consent (Dent, Sussman, and Stacy 1997; Esbensen et al. 1996; Moberg and Piper 1990; Pokorny et al. 2001). Yet none of these offered insights into the rationale of IRBs or prescriptive advice for researchers.

To be sure, there is nothing unethical or even remotely wrong with not directly addressing the practical aspects of IRB oversight. But the absence of clear guidance is somewhat surprising, given the increasing role of IRBs in evaluation science. The word *somewhat* is apt because whereas an electronic Medline literature search for *IRB* yielded 2,110 articles, only a handful appear to offer any guidance on IRBs.[6] And no articles guiding social scientists were found in searches of Medline or major social scientific data bases (e.g., ERIC, Infotrac Expanded Academic Index, and Social Science Index). It seems that frustrated researchers prefer to complain about IRBs rather than understand them or help colleagues through the process.

This article aims to assist evaluators struggling to understand and work with IRBs.[7] My goal is to foster better communication and collaboration between social scientists and IRBs. In short, I argue that IRBs are under new pressure to scrutinize social scientific research and that frustration emanates from a fundamental rejection of their legitimacy. Remedy lies in educating ourselves about IRBs and educating IRBs about our methods and the risks

they pose—a peer-education process to better protect research subjects. Concluding remarks incorporate tips for submitting protocols to IRBs.

Whether my causal theory is correct is of no great consequence. At worst such assertions are a useful pedagogical device. Nor does this article depend on high levels of frustration; given the prominence of IRBs in evaluation science, even the enamored may benefit. What is more, it should be obvious that no article-length treatment of these very complicated issues can be comprehensive. Even if I understood all of the issues I could not address them all here. A conversational style is occasionally adopted to simplify the complex.

THE PROBLEM

Although good interactions remain the norm, social scientists have expressed profound frustration with IRBs (Hessler, Galliher, and Reynolds 1983; Murray 1998; Niemonen 2000; Ross et al. 2000; Shea 2000; Timmermans 1995; Warren and Staples 1989). I am aware of complaints that IRBs are obstructionist, irrational, inconsistent, foolish, and even malicious.[8] For example, one social scientist claimed the IRB was racially biased because it questioned his or her intentions to interview Native Americans without providing the standard recruitment protocol or obtaining standard informed consent. Another reproved the IRB for compelling him or her to notify subjects that their data was used without consent, despite health consequences. Because it questioned the risk/benefit ratio of a survey question tapping "memories of freedom" in a prisoner study, another investigator insisted that the IRB overstepped its authority. Another wrote that he or she was personally offended when an IRB questioned his or her focus group study of the sexual experiences of female college freshman where the focus group was moderated by more senior male students in a small college setting. Still another researcher found an IRB stipulation that he or she encrypt identifiable data being sent through the Internet overly burdensome. More troubling are examples of powerful scientists and administrators trying to influence the IRB's decisions.

de Sola Pool and others would attribute these conflicts to the illegitimacy of an IRB review (de Sola Pool 1980; Seiler and Murtha 1980). Pattullo (1984) and Mosteller (1980) would link such frustration to the IRB's overestimation of risks posed by social science protocols. Levine might attribute such conflict to an IRB's inexperience with social scientific methodology (Levine 1980, cited in Hoppe 1984). Sieber (1992) would likely argue that the frustration stems from the poor ethical training most social scientists

receive and inconsistent IRB decision making. Timmermans would say something about the IRB's desire to promote positivist science and maintain the status quo (Timmermans 1995). Woodward (1999) would suggest that scientists are subordinating subject protections to utilitarian efficiency and economic pressure. In any case, I assert that there are two reasons, which when taken together explain why such sentiments appear to be increasing:

1. Regulations were developed for biomedical research.
2. Interpretations of regulations have become more strict.

MEDICALLY ORIENTED REGULATIONS

There is an odd fit between IRB regulations (discussed below) and social research methods. Although ethicists rightly claim that the regulations should apply to all types of research, the fact is that the regulations on which IRBs rely were written for and by biomedical researchers trying to protect subjects from the physical risks of surgical and pharmacological experiments. This lineage continues to affect the entire human subjects protection system for it influences the make up and focus of IRBs, the training of IRB members and researchers, informed consent forms, rules about recruitment and data access, and the like. Biomedically focused IRBs are understandable because such studies may pose grave risks. But the focus and culture create problems for social scientists whose applications are no less important to them and perhaps to society at large. That most evaluations employ methods (e.g., surveys) about whose risk we know little about means that practical problems for petitioners and IRBs arise. There remains little regulatory guidance on qualitative (e.g., ethnographic or oral history; Bliss 2002; Gallant 2002; Parrott 2002) or survey research (Oakes 2002).

History illuminates. As mentioned above, federal IRB regulations were motivated by bioethical considerations of the horrific Nazi doctors' experiments and unrelated American violations. Prior to 1938 there were no federal restrictions on human experimentation (Peckman 2001). Today's IRB evolved from informal hospital-based and National Institutes of Health (NIH) committees set up by local researchers who believed oversight was critical to ethical research. At least as early as 1954, NIH paid close but informal attention to protecting its intramural research subjects (Curran 1969). In 1966, it formalized the process and established IRBs as a fundamental component of NIH research. In 1974, the Department of Health, Education and Welfare (DHEW) raised NIH's human subjects policy to regulatory status and gave it the teeth of financial control. The promulgation of the 1974

National Research Act established the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research. In 1978, the National Commission published recommendations for the establishment of IRBs (see Federal Register, Vol. 43, p. 56174 [cited hereafter as 43 FR 56174]).[9] In 1979, it issued its groundbreaking *Belmont Report*, which outlined not only the three fundamental principles of ethical research—respect for persons, beneficence, and justice—but also the foundation for all IRB activity.[10]

In August 1979 (44 FR 47688), DHEW proposed guidelines that required social research, regardless of funding source, to receive a comprehensive IRB review equal to that of biomedical research. Never having been consulted, social scientists voiced strong protests and argued that such restrictions did not square with the risks of social inquiry. Some were vociferous, claiming that the regulations violated their First Amendment rights, were open to gaming, and raised the specter of McCarthy era witch hunts (de Sola Pool 1979, 1980; Seiler and Murtha 1980; see also Gray 1982; Levine 1979; McCarty 1984; Pattullo 1984; Tropp 1982).[11] Others more reasonably argued that the new rules were fashioned without evidence of physical harm in social scientific research (Casell 1980; Mosteller 1980; Pattullo 1984).

In May 1980, DHEW became the Department of Health and Human Services (DHHS). In 1981, DHHS promulgated significant revisions to their human subjects regulations. These regulations are codified at Title 45, Part 46, of the Code of Federal Regulations (45 CFR 46). Importantly, the final 1981 rules permitted exemptions and expedited review procedures that satisfied many social and behavioral science researchers (discussed below). A 1991 revision (56 FR 28003) was important because it essentially required IRBs to review all research at institutions receiving federal grant funds. At that time, 16 federal agencies formally adopted the core of these regulations, which became known as the Common Rule.

The reason that social scientific evaluations are subject to a biomedically dominated IRB system thus lies in the historical evolution of IRBs and corresponding regulations. From the very beginning, social scientists were required to comply with rules they were essentially excluded from developing (Pattullo 1984; Tropp 1982).[12] Theoretically, this should not matter. Regulations are and should remain based on risks, not academic disciplines. Indeed, there is no legal or regulatory basis for making a distinction between social and biomedical research; federal regulations do not mention either term (Amdur and Bankert 2002b). But practically, it seems to matter a lot—at least to frustrated evaluators and some confused IRBs.

Figure 1 shows the disciplinary spectrum of typical risk posed to research subjects, exceptions notwithstanding. On one side there is journalism; on the

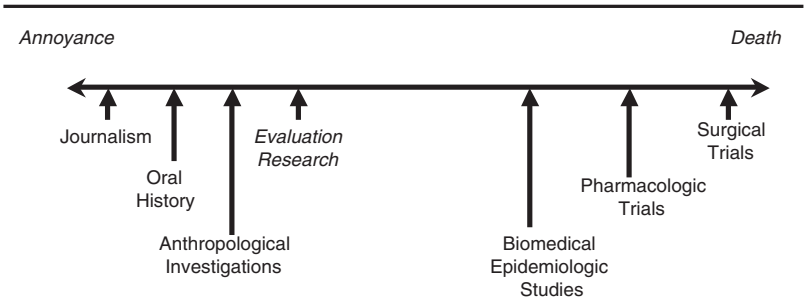

Figure 1: Typical Risk Spectrum by Research Discipline

other, surgical trials. We know a fair amount about the physical risks to the right; the IRB system was set up to address these. We know little about the nonphysical risks to the left, and this creates problems. How do we measure and weigh an annoying journalistic inquiry? What about a threat to confidentiality? Deception? Sensitive questions about illegal drug use?

Historically, nonphysical risks were never a problem because everyone pretty much ignored them. No more. In recent years IRBs have shifted their attention to include nonphysical risks. This was prudent and subjects enjoy more protection. But it also creates problems because IRBs know very little about such risks or the methods that create them. Consequently, IRBs must speculate and make decisions on the basis of worst-case scenarios. The word *must* is important because, just as in the absence of a surveillance system to detect infections, the absence of data on risks and wrongs in social scientific research does not prove that subjects go unscathed.

What risks does social scientific research pose? Included are the invasion of privacy, loss of confidentiality, psychological trauma, indirect physical harm, embarrassment, stigma, and group stereotyping. These are serious and merit serious consideration (Prentice and Gordon 2001; Warick 1982). Consider that revealing the name of a female subject in a domestic violence program evaluation, even if inadvertent, may give the batterer enough information to attack. Or that an ostensibly benign psychosocial survey may cause flashbacks or trigger depression in unstable subjects.[13] Humiliation, stigma, and embarrassment may be caused if identifying information is leaked or improperly secured.[14] Criminal penalties may arise in evaluations of underage alcohol or other drug use. There is nothing benign here.

Although typically less severe, observable, and perhaps foreseeable, social scientific risks are risks nonetheless. Suffice it to say that our medically

dominated IRB system has yet to properly address nonphysical risks and the methods that create them. It is not clear when this will change.[15]

IRBs ARE BECOMING STRICTER

Perhaps the overarching reason for conflict and misunderstanding is that today's IRBs are more resolute. It seems the change has occurred within the past 3 to 5 years. The reasons for this are not arbitrary, bureaucratically pernicious, or censoring. Rather, increased scrutiny is due to a credible threat by the Office of Human Research Protections (OHRP) to suspend all of a noncompliant institution's federally funded research, and the very real threat of legal actions against not only institutions but also IRBs and investigators. And government reports criticizing IRBs with proposed fines up to $1 million (Brainard 2000b; GAO 1996; Phillips 2000; Wadman 1998a, 1998b).

Although extremely rare and highly controversial, the OHRP (see below) has suspended research at institutions found to be out of compliance. Commentators have called such suspensions the "death penalty" and the "hammer method" (Brainard 2000a). If suspended, no federally funded research may continue: Participants cannot receive treatments, enroll, or be recruited; results from time-sensitive studies cannot be reported; and data cannot be analyzed. Suspension means that there is no money to pay graduate students, travel to conferences, or purchase equipment. It means researchers may lose months, if not years, of work. Severe effects to an institution's reputation may dislodge the public's willingness to participate in research or an outstanding scientist's interest in an association. The former point is critical as there is mounting evidence that ethically improper research, by anyone, devastates a social scientist's chance to recruit from affected communities long into the future (Fouad et al. 2000; Freimuth et al. 2001).

The list of institutions with ethical violations in the past 5 years is a veritable "who's who" of biomedical research. Table 1 notes select high-profile cases. No doubt motivated by physical risks, a careful review shows that the reasons for the actions are not limited to biomedical protocols. Failures of full disclosure, recruitment, informed consent, strict interpretation of regulations, risk-benefit considerations, and misuse of vulnerable populations are equally likely in social scientific studies. Sadly, an OHRP audit would likely find any research organization wanting.

It is not important whether one believes evaluation research protocols are actually putting lives at risk or whether the government and IRBs are overstepping their authority and behaving irrationally. What matters is that institutional administrators, IRBs, and savvy researchers fear suspension and loss

TABLE 1: Select High-Profile Suspensions and Citations for Ethical Violations in Research

April 1998	Office of Protection from Research Risks (OPRR) cites the University of Maryland at Baltimore for "certain systemic weaknesses [in its protections for human research subjects]." The citation acknowledges that although informed consent documents "generally complied" with federal requirements, there were several documents that failed to properly inform subjects about research risks.
October 1998	OPRR suspends research at Rush–Presbyterian–St. Luke's Medical Center in Chicago, citing improper subject enrollment. Some subjects were ineligible because of preexisting symptoms; one died after an experimental treatment.
May 1999	OPRR suspends research at Duke University Medical Center after federal investigators determined that the university could not ensure the safety of subjects. OPRR found the administrative aspects of Duke's Institutional Review Board (IRB) inadequate.
August 1999	The Chancellor of the University of Illinois Chicago resigns after an OPRR suspends research. Violations include failure to obtain proper informed consent from all subjects in research projects and failure to obtain IRB approval before beginning research.
September 1999	Office of Human Research Protections (OHRP) suspends gene-therapy trials at the University of Pennsylvania, where Jesse Gelsinger, aged 18, died in a gene-therapy study. In November 2000, the Federal Drug Administration (FDA) notifies researchers that it had found evidence of numerous violations of the rules for conducting the research project. FDA notified the Principal Investigator he "repeatedly and deliberately violated federal regulations" and that the agency was moving to bar him permanently from conducting further drug research on human subjects.
January 2000	OPRR cites researchers at Virginia Commonwealth for mailing inappropriate questionnaires that asked twins sensitive questions about their family histories. Such proxy surveys raise numerous ethical concerns.
January 2000	OPRR suspends research at the University of Alabama at Birmingham where regulators determined that the IRB had not followed all mandatory requirements. In particular, regulators said that the board had rarely discussed how to minimize risks to subjects and ways to protect subjects' confidentiality.
July 2000	OHRP suspends research at the University of Oklahoma, citing numerous deficiencies in the treatment of subjects in a skin cancer study. Findings include failure to disclose to subjects and regulators that safety risks had been discovered and the misrepresentation of benefits. This was the OHRP's first action since evolving from OPRR.

(continued)

TABLE 1 (continued)

September 2000	OHRP suspends research with prisoners and juvenile detainees, subjects at University of Texas and University of Miami, respectively. Regulators also directed the University of Florida and Yale University to improve their oversight procedures for prisoner research.
June 2001	OHRP suspends research at Johns Hopkins, the leading recipient of government research fund, when an otherwise healthy young woman died in an experimental asthma therapy trial. Hopkins admitted that they did not do what moral researchers must do in such experiments—obtain an iron-clad informed consent and have an in-house committee carefully monitor all experiments that are done simply to obtain knowledge and not to benefit the subject.

SOURCE: Data retrieved from various issues of the *Chronicle of Higher Education*, *New York Times*, the *Washington Post*.

of public trust (Brainard 2000a). That the heightened scrutiny for social scientific protocols is the consequence of violations in the biomedical sciences is of little import, especially, it seems, to the public.

Beyond the threat of regulatory action, legal proceedings are also forcing IRBs to more closely scrutinize protocols. A few examples illustrate that the issues at hand again end up being about informed consent and risks posed in nontherapeutic research.

In the late 1980s, the University of South Florida defended itself from a class-action lawsuit. Plaintiffs alleged that the institution conducted improper research on 280 pregnant and poor Spanish-speaking women. This case did not stand on federal funding or any physical harm to the subjects, but rather on the grounds that researchers failed to obtain and document adequate consent.

The Maryland Court of Appeals recently delivered a scathing opinion of an Environmental Protection Agency–funded evaluation of lead-paint abatement programs in the 1990s (Curry 2001; Nelson 2001). The Court accused Johns Hopkins's affiliated researchers of inadequately informing participants about the study risks and of using children like "canaries in a coal mine." It is no exaggeration to say that the Court's statement set a new standard of protection for children in nontherapeutic studies. The Court also accused the presiding IRB of helping researchers circumvent federal regulations. Finally, and alarmingly, the Court held that an informed consent document is a binding legal contract that permits remedy through not only tort but also contract law.

There are many other lawsuits pending and being settled out of court. Named defendants include not only universities and their affiliates but also IRBs and investigators alike (Reinsch 1984). Lawyers see an opportunity not only to change the system but also to enjoy the financial rewards of doing so. One stated that he intends to use the law to reform a system that often neglects the rights of people who agree to participate in medical experiments and hold IRBs and investigators personally accountable for violations. The same attorney went on to say that he plans to keep the lawsuits coming and that "there is a lot of money to be made [by doing so]" (Blumenstyk 2002). Some legal scholars say we soon should expect juries to grant not only remedial but also punitive damages (Delgado and Leskovac 1986).

Finally, more legislation to better protect data privacy is imminent. The Health Insurance Portability and Accountability Act (HIPAA) appears likely to place new restrictions on a researcher's access to medical records and to require informed consent before a researcher can access them (Annas 2002; Kulynych and Korn 2002). Many conducting health-related social scientific research (e.g., epidemiology) view this as a violation of their right to conduct research and improve the public's health (Kulynych and Korn 2002). Yet in writing the HIPAA rules, Congress relied on clear evidence of privacy violations and several surveys indicating the public's wish to balance privacy and research (65 FR 82381).[16] Case law is clear that regulating the acquisition of information is neither a violation of the First Amendment nor an unjustified infringement on academic freedom (Robertson 1982). Because IRBs are already strict and the statute permits waivers of consent, this legislation offers little in the way of extraburden. In any event, HIPAA itself should have little effect on evaluation research. It is, however, a strong signal (Boruch, Dennis, and Cecil 1996).

THE RESULT: $a + b = f$, WHERE f INDICATES FRUSTRATION

Because we still know very little about nonphysical risk, prudence must subjugate anecdotal accounts of safety and any efficiency arguments. The reason for the increased scrutiny is that our biomedical colleagues have made costly mistakes that neither legislators, universities, institutes, IRBs, fellow researchers, nor human subjects can absorb. The result is a system forced to look hard at new risks on which little data exist.

Why are social scientists frustrated? It is not clear and may not matter too much. But whereas my view incorporates some of those expressed above, I think something more fundamental is at work: I am unconvinced that researchers truly appreciate that it is legal, ethically sound, and scientifically

legitimate for IRBs to mediate the relationship between scientists and their subjects. In short, many researchers still believe, perhaps subconsciously, that they have an inalienable right to research. That is, they have the right to research other humans without interference from an IRB. To the extent a researcher believes he or she holds a right to research, he or she will find IRBs anywhere from annoying to infringing on Constitutional rights.

It follows that arguing that IRBs are inherently obstructionist or overstepping their authority overlooks the fact that the "property rights" question has been asked and answered: Researchers do not have an inalienable right to conduct research with human subjects (Cardon 1984; Hammerschmidt 1997; Peckman 2002; Robertson 1978, 1979, 1982). Claims of illegitimacy, even if subconscious, are an unnecessary social cost and distract us from improvements (Coase 1960; Demsetz 1964). IRBs are peer/community review mechanisms analogous to journal editors who require changes to an article or NIH/National Science Foundation (NSF) scientific review groups who determine the fate of grant applications. Just as we have no inalienable right to force *Evaluation Review* to publish our work or compel NSF to award us taxpayer money, we have no inalienable right to research others. That scientists are constantly required by others to make (occasionally silly) changes to their work but squawk and flap loudly when IRBs require the same is astonishing.

This is not to say that IRBs are perfect or free of the ludicrous. They do make mistakes and need to do a better job at collaborating with and educating investigators. But the important point—that we must never lose sight of—is that despite origins, motivations, and any current failures, it is necessary for IRBs to review social scientific research.

THE SOLUTION

What can an evaluator do to alleviate frustration with increasingly stringent IRBs? There is only one answer: educate himself or herself about IRBs and educate IRBs about research and its risks (and then volunteer to serve on one!). Investigators well versed in the *Belmont Report* and more technical IRB procedures rarely need to dispute decisions, and when they do it concerns how known rules are interpreted or what is best for the subjects. It follows that a great deal of frustration may be eliminated by careful study of basic IRB regulations and issues. Education seems to modify frustration in the researcher-IRB-subject chain. As with the ultimate responsibility for protecting research subjects, the onus for improvement and change lies with the researcher(s). Accordingly, I now offer some value-added basics and then

discuss accommodations especially relevant to social scientific evaluations. Note well that while offering insights and practical advice on IRBs and current regulations, I emphatically believe that the ultimate focus must be on protecting research subjects, not interpreting and exploiting the rules. For me, what follows appears to be a necessary step along the way.

IRB BASICS

Whereas the *Belmont Report* provides the ethical foundations for them (Vanderpool 2001), the principal IRB regulations are codified at 45 CFR 46. It seems that every university posts these on their publicly accessible Web site. They are always available on the OHRP Web site: http://ohrp.osophs.dhhs.gov. The regulations are not long and are well worth careful study, especially if the goal is to minimize a frustration quotient. Shelton also offers a nice summary (Shelton 1999).

Who is the IRB? By regulation, IRBs must have five or more people and be diverse, so as to have expertise in relevant areas of research. Many also aim to reflect the subjects under study. Typical IRBs are composed of professors, physicians, other scientists, lawyers, ethicists, nurses, and at least one nonscientific community person. IRBs are composed of our peers who volunteer their time to protect human research subjects. In addition, there is usually an IRB administrator—a professional who manages the business activities of the board.

What is research? This is not a silly question as the boundaries between research and practice are often blurred. Practice generally refers to interventions designed to help an individual subject's well-being. Research is intended to develop or test a hypothesis or contribute generalizable knowledge. Research usually involves some sort of formal protocol that sets forth an objective and a set of procedures to meet it (Penslar 1993).

What is a human subject? Human subjects are living individuals about whom an investigator (professional or student) conducting research obtains (a) data through intervention or interaction with the individual or (b) identifiable private information. Recent definitional complications come from investigations into biological samples (Merz, Leonard, and Miller 1999; Woodward 1999) and deceased persons' information that may bear directly on survivors. For example, research into whether a program to assist AIDS patients with end-of-life events may collect data on subjects after their death. This information is important to a surviving partner who may face social and economic discrimination long after their loved one's demise.

What agency is in charge of human subject protections and IRB oversight? The OHRP is the federal government office with IRB oversight responsibility. It has a staff of 30, and its director reports directly to the assistant secretary for Health, DHHS. OHRP has the authority to halt all federally funded research activity at institutions violating IRB regulations. Prior to June 2000, this office was called the Office of Protection from Research Risks, and was located in the Office of the Director for Extramural research at NIH (see http://ohrp.osophs.dhhs.gov/).

What is equipoise? Equipoise is a state of indifference or genuine uncertainty about the comparative merits of a policy or program, or about the direction of effect estimates, under (experimental) investigation. Such a state is fundamental to ethical research. Indeed, the purpose of research is to collect and analyze evidence so as to overcome equipoise. If an investigator believes, ex ante, in the superiority of one treatment/program over another, she must suspend this belief during research or risk biased results. At least two implications arise: (a) it is unethical to withhold (via placebo) known and available effective treatment programs from needy subjects, and (b) it is unethical to promise research subjects a benefit from a treatment being evaluated.

What is minimal risk? Again, this vague idea is controversial (Prentice and Gordon 2001; Woodward 1999). But according to regulations, a risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life (45 CFR 46.102). Minimal risks are referenced to a normal adult healthy person; adjustment for illness or disability is not permitted (Oki and Zaia 2002). Minimal risk usually figures prominently in evaluation research applications because it triggers the possibility of an expedited review (see below).

Who are vulnerable subjects? There are several official designations and other unofficial ones. These are important because a great deal of research focuses on the least advantaged and most vulnerable among us. Officially, vulnerable subjects include pregnant or possibly pregnant women and their fetuses (Bowen 2002); prisoners (Hornblum 1997; Prentice et al. 2002); and children (Nelson 2002). Unofficial groups include racial/ethnic minorities, college students (Tickle and Heatheton 2002), and adults with decisional impairments (Delano 2002). Regulations limit research with vulnerable populations that exceeds minimal risk. There is increasing discussion about the usefulness of the current approach (Kipnis 2001).

Is IRB review necessary? As discussed below, some studies are exempt. Nonetheless, the short answer here is *yes*. Even if you think your study is not subject to oversight, it is usually best to talk with your IRB administrator or submit an application. Letting an IRB decide if your study requires oversight

is a good idea because the costs of conducting "ethically improper" research far exceed the temporal benefits of deciding for yourself. Although most pilot studies must be reviewed, neither fine-tuning a questionnaire nor testing equipment or procedures usually requires review (Sieber 1992).

SPECIAL REVIEW CATEGORIES

Two special review categories were developed specifically for social scientific research (McCarty 1984). I am aware of no systematic data, but I agree with early estimates that some 80% of social scientific protocols enjoy these categories (McCarty 1984). Not loopholes, these accommodations were promulgated to balance the risks posed to subjects in social scientific research and the benefits to society of the same. These categories figure prominently in evaluation research protocols and merit careful study.

Exempt Research

Not all research falls under the purview of an IRB. But because regulations are open to interpretation (Pritchard 2001), most institutions believe that only an IRB can determine if a study is exempt. There is no great gain in seeking this status except that investigators are freed from ongoing (e.g., annual) review. But ongoing review is not overly burdensome and serves to remind us of important values. Moreover, exemption does not mean ethics may be abandoned: "Exemption does not imply that investigators have no ethical responsibilities to subjects in such research; it means only that IRB review and approval of the research is not required by federal regulations" (Penslar 1993, 3).

Regulations at 45 CFR 46.101(b) outline what research is and is not covered. This subsection is summarized in Table 2. Explaining and enriching the raw code should prove useful (see Pritchard 2001).

The first section, §46.101(b)(1), deals with normal educational practices and settings. The intent here is to permit teachers to evaluate students and evaluators to evaluate normal teaching curricula absent IRB oversight. Evaluations of radically new educational strategies are not exempt, nor is research involving deception or novel physical exercises (DuBois 2002; Prentice and Oki 2002).

§46.101(b)(2) may be the most important for evaluators. It means that survey research is exempt from oversight unless identifying information is collected and the disclosure of such information may cause harm to the subjects.[17, 18] Simply put, anonymous and harmless surveys are exempt; so, too,

TABLE 2: Categories for Exempt Status - 45 CFR 46.101(b)

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
(i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:
(i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:
(i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

(6) [Food Evaluations]

are observational studies.[19] There remain debates regarding the precise meaning of these terms (Goodman et al. 1999), but it seems clear that Gallup Polls and other benign survey research is not subject to review.

§46.101(b)(3) goes on to say that research on elected officials and research that enjoys strict federal confidentiality protections are both exempt from IRB review. Also exempt are surveys on groups, organizations, and associations, which are sometimes called establishment surveys. The reason for this is that organizations are not human subjects. Be aware that to learn

who filled out a questionnaire, many establishment surveys query the respondent. Such questions may preclude the exemption.

§46.101(b)(4) deals with collection or analysis of existing data. Exempt is research with publicly available data sets or those stripped of identifying information. This is the most commonly used category I see. Prentice and Oki (2002) correctly emphasized that investigators often fail to realize that data without names do not necessarily mean subjects are not identifiable. Data must also be in existence before the study begins.

§46.101(b)(5) is often misunderstood. With approval, evaluators may seek exempt status for research on publicly funded social programs (such as Medicaid, unemployment, and Social Security) that tests the delivery of an already proven program (Tropp 1982). Experiments testing an intervention are not exempt. This subsection does not appear to apply to nonpublic or local programs, but it is not clear.

Expedited Review

Because IRBs typically meet once a month, investigators must often wait 4 to 6 weeks for an IRB decision. If changes are required and/or honest disagreements obtain, the time between submission and approval can be considerable. Regulations provide for a faster review process called expedited review (see 46 FR 8392; Oki and Zaia 2002).

Expedited reviews are usually performed continuously on a first-come, first-serve basis. Experienced administrators triage applications and ask senior IRB members to review protocols thought to meet specified conditions. In expedited reviews, only one or two seasoned reviewers ensure that the protocol conforms with ethical standards and exercise oversight on behalf of the entire board. If, on review, a reviewer determines that a protocol does not meet specified conditions or has other concerns, he or she may remand the application to the full board. Only a full board can disapprove a study and only after a carefully documented review.

Two kinds of IRB applications may exploit expedited procedures: (a) new applications that pose no more than minimal risk and meet other requirements, and (b) minor changes in previously approved protocols. I shall say nothing more about the latter. Although there appears to be a disturbing trend to add more (Woodward 1999), there are currently nine kinds of minimal risk research that satisfy the former (63 FR 60364). The first three of these are biomedically related; the last two concern ongoing review. The middle four appear most important to social scientists. Table 3 summarizes these.

TABLE 3: Relevant Categories for Expedited Institutional Review Board (IRB) Review

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving X rays or microwaves.
5. Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).
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.

SOURCE: Federal Register, Vol. 63, p. 60,364.

A great deal of social scientific research conforms to the requirements of condition seven. Surveys, focus groups, unstructured interviews, ethnographies, and other such social research methodologies that are not otherwise exempt often fit here. Condition six covers commonly employed audio- and video-taping procedures. Together, these two conditions permit speedy review for the bulk of minimal risk social scientific research.

THREE COMPLICATING ISSUES

Although a basic understanding of IRBs and their review imperatives will go a long way toward alleviating any frustration, resolution will require something more. Several subtle issues complicate IRB reviews and three of these directly effect evaluation research protocols: subject recruitment, informed consent, and confidentiality. Although related to the voluntary nature of ethical research, these present somewhat distinct issues. Mastery will bring us closer to collaboration.

RECRUITMENT

Recruiting subjects is often one of the most challenging aspects of research. Nonrandom subject selection can bias parameter estimates, and an insufficient number of subjects inflates Type II error. Unlike some clinical

research where physicians have regular access to subject pools, recruitment in evaluation studies is often an expensive and exhausting task. Past ethical violations continue to aggravate recruitment in minority communities (Fouad et al. 2000; Freimuth et al. 2001).

IRBs typically examine two related recruitment issues. The first concerns an equitable selection of subjects (Davis 2002; Kahn, Mastroianni, and Sugarmen 1998). Regulations compel IRBs to ensure this (45 CFR 46.111[a][3]).[20] The reasons for this are again historical and complicated. Until the 1970s, the burdens of ethically challenged research fell largely on the poor and marginalized while the advantaged enjoyed the benefits (Penslar 1993). The most dramatic illustration of this is the aforementioned Tuskegee study. From about 1975 to 1994, very little research was conducted with women or racial/ethnic minorities. This meant that these groups were again excluded from enjoying benefits. In an effort to achieve balance, regulations now require that research protocols include racial/ethnic minorities and women so that findings may benefit them, too (Davis 2002; Penslar 1993). Whenever possible, evaluators should follow the principle that those who bear the burden of being research subjects enjoy the fruits.

The second recruitment issue concerns the coercion of subjects by researchers. This is no small matter, as researchers have an obvious interest in gaining subject participation and coercion is a subtle thing. For example, psychology students are often asked to participate in research but when participation is tied to grades, an element of coercion and conflict of interest obtains. What is more, in typical evaluation studies, clear power differentials between researchers and subjects exist. And although it is sometimes necessary, paying third parties a bounty to recruit subjects is troublesome. IRBs aim to balance the competing interests. That body language, credentials, and speech influence decisions to participate cannot reasonably be questioned (Sieber 1992). This is why IRBs generally prefer indirect (e.g., telephone and letter) to direct interpersonal recruitment strategies.

Despite evidence suggesting that indirect contact needlessly hampers recruitment (Roberts, Newcomb, and Frost 1993; Savitz et al. 1986), some IRBs are so worried about coercion that they insist on indirect recruitment through various forms of advertising. How should this be done? Homer, Krebs, and Medwar (2002) provide an exceptionally good discussion of how best to use advertisements in subject recruitment. Their advice: (a) clearly state that the project is research; (b) err on the side of underestimating benefits and overestimating risks; (c) do not make claims of safety, equivalence, or superiority; (d) avoid phrases like *new treatment*; (e) avoid the term *free*; (f) do not use dollar signs or focus on monetary issues; and (g) obtain approval from all applicable groups to post the advertisement.

The tension between the need to recruit and retain research subjects and the obligation to protect them from coercive interests makes compensation another difficult topic. Penslar (1993) pointed out,

> Federal regulations governing research with human subjects contain no specific guidance for IRB review of payment practices. One of the primary responsibilities of IRBs, however, is to ensure that a subject's decision to participate in research will be truly voluntary, and that consent will be sought "only under circumstances that provide the prospective subject . . . sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence." [Federal Policy §46.116; 21 CFR 50.20] (P. 28)

Several thoughtful discussions of the ethical aspects of compensation for research subjects exist (Dickert and Grady 1999; Russell, Moralejo, and Burgess 2000). Social scientists have also addressed the issue, but from an instrumental perspective to increase participation rates (Burstein, Freeman, and Rossi 1985; Dillman 2000; Singer 1978a, 1978b; Singer and Frankel 1982; Singer, Van Hoewyk, and Maher 2000). Although the questions are many, the answers are few. For example, how much compensation, if any, should an investigator offer in a study of homeless drug or alcohol addicts who will only be interviewed once? What form of compensation should be offered? Cash, food, or clothing? Anonymity is breached if payment is by check, and many lack the ability to cash checks. When should the payment be made? Before or after completion of the survey? Must all questions be answered to receive a completion bonus? It is unclear how best to balance ethical recruitment and methodological imperatives.

As outlined below, my view is that the answers lie in (perhaps future) empirical results, and that evaluators may justify their subject compensation accordingly. It seems clear that the potential for coercion is reduced when between $1 and $5 is included up front in a mail survey, as opposed to promises of payment when some task is complete. Evidence suggests this may be sufficient to gain required response rates in short cross-sectional studies (Aday 1996; Dillman 2000). On a related matter, evidence suggests that lotteries (i.e., the chance to win a larger prize) may be coercive because not all subjects understand probability. In an experiment, Carlson (1996) compared an included $2 bill with a chance to win $300 and found no appreciable response rate difference. Relying on social exchange theory, Dillman (2000) thought that lotteries only offer an indirect payment for services while included payments engender a feeling of the need to reciprocate.

INFORMED CONSENT

Informed consent is one of the primary ethical requirements underpinning research with human subjects. It reflects the basic principle of respect for persons that the Nazi doctors heinously ignored (Burt 1996; Holmes-Farley and Grodin 1998; Penslar 1993). Informed consent was articulated as a legal and ethical principle for medical research in 1972. But it still receives criticism by social scientists, largely because it is believed that social research poses no risks or that the principle is too Anglo-American for certain subcultures (Fluehr-Lobaan 2000; Marshall 1992; Newton 1990).[21] Yet, except for the early work of Singer (Singer 1978b; Singer and Frankel 1982), few have examined this issue scientifically.

One of the IRB's most important activities is to weigh, in light of risks and benefits, the information provided to potential subjects. Whether the information is deemed adequate partly depends on the impression being conveyed (Penslar 1993). Impressions matter because serving as a human subject is not a duty; the decision whether to volunteer must rest entirely with a prospective subject who must usually rely solely on the information investigators offer. Moreover, although there are few legal restrictions on observing public activities or tabulating public records, doing so without informed consent stretches our ethical imperatives and may further erode the public's trust in social research.

What factors enter into the subject's decision to participate in a research study? Presumably an important one is the costs and dangers associated with the research. For this reason, informed consent rules require disclosure of known and foreseeable risks (Delgado and Leskovac 1986). Another factor is the potential benefits. Because evaluation research is nontherapeutic, more often than not the only benefit is the subject's satisfaction from having done something altruistic. This benefit, however, is denied when a subject does not autonomously choose to participate or chooses to participate without complete information (Delgado and Leskovac 1986).

Most investigators do not seem to appreciate that informed consent (a) must be meaningful and (b) is an ongoing process, not merely a document or a moment (Brody 2001). Regulations stipulate that subjects may withdraw from research at any time without repercussion. For this to be meaningful, subjects must always be aware of the status of the ongoing study and their place in it—approved deception studies notwithstanding. Informed consent is thus a continuous state of affairs; signed informed consent forms are (typically) necessary but not sufficient.

Informed consent forms (ICFs) are too often impenetrable by even the most intelligent scientists, much less disadvantaged subjects. Among others, Hammerschmidt and Keane (1992) show the dismal quality of ICFs (see also Sugarmen et al. 1999). In nearly every case, reading levels are too high, jargon too common, and potential risks woefully underestimated. This is especially true in consents for children, which are called assents.[22] Of course I have said nothing about the many cognitive issues associated with such documents (Stanley and Guido 1996; Thompson 1996).

Although controversial (Woodward 1999), there are circumstances where IRBs will waive requirements for a signed ICF from each subject. In short, to receive a waiver of consent, studies must pose no more than minimal risk to nonvulnerable subjects. A waiver may also be granted if the signed document actually increases risks (Cardon 1984; Elliott 2002) or is culturally inappropriate.

A few new problems associated with informed consent appear uniquely relevant to evaluation science. Consider cluster or group-randomized trials that assign whole groups—such as classrooms, cities, or workplaces—to treatment conditions and then intervene on environmental conditions (Donner and Klar 2000; Murray 1998). How should we gain informed consent from a group/cluster? Although insufficient, Donner and Klar (2000) contribute the most comprehensive discussion of this problem and rightly point out that strict adherence to IRB guidelines might require ex ante informed consent from each and every group member. This seems logistically impossible and therefore preclusive of such research. But how are we to handle, say, 1 refusal out of 1,000 acceptances? What of the opposite? Should the views of the one override those of the many? Is a 50.01% majority vote sufficient to claim consent? This issue is not so much about an individual in a group refusing to complete a questionnaire or attend an educational session. Such situations are relatively easy to deal with (Kobokovich, Bachir, and Stanton 2002; Pokorny et al. 2001). Rather, this issue is about altering a classroom's curriculum or a city's park system where not everyone agrees that this is an intervention worth testing. Perhaps group leaders have the right to consent on behalf of a group. The Council for International Organizations of Medical Sciences basically recommends that consent should rest with the responsible publicly elected authority. Sieber (1992) believed it is appropriate to work with and gain consent from community gatekeepers. Strauss et al. (2001) suggested that community advisory groups may be most helpful. But the larger the group, the larger the problem of gaining meaningful consent. It remains unclear how this should be handled.

Related to this is the problem of participatory research and empowerment evaluations. These designs aim to include subjects as researchers with directive input. Again, it is unclear what role an IRB process should play here. Much like ethnographic research (Parrott 2002) and applied anthropology (Marshall 1992), it is unclear on how proper informed consent should be accomplished and maintained. Community-based research may require a new approach to informed consent (Kagawa-Singer 2000).

CONFIDENTIALITY

Rights to confidentiality may be distinguished from rights to privacy by noting that confidentiality implies that voluntarily surrendered information must be used only in the agreed upon manner; privacy implies that no consent for discovery is granted (Beauchamp and Childress 1994). Informed consent is required to protect privacy. Anonymity is the best assurance for protecting confidentiality.

Informed consent documents too often unconditionally assure subjects that their identities will be protected. Such assurances are good for they protect, inter alia, a subject from blackmail, personal attacks, subpoenas, and embarrassment (Sieber 1992). But although researchers often complain that privacy and confidentiality rules restrict their research, a major concern for IRBs is that investigators (a) do not do enough to protect identifying information and (b) promise too much confidentiality.[23]

Maintaining the confidentiality of identifying information (IDs), such as names, addresses, and social security numbers, is fundamental to ethical research. Fortunately, it is also relatively easy to do. Traditional statements about storing raw data in locked file cabinets are insufficient, for computers are now (globally) networked and too often unsecured. I suggest the following steps to protect confidential information. First, shred any hard-copy forms as soon as possible. If research designs require IDs to be retained—and many do not—delink them from main data sources at the earliest possible instance. Use arbitrary IDs to bridge between the confidential and now anonymous information. Encrypt confidential ID files and destroy them as soon as possible.[24] Unencrypted data must never be e-mailed or otherwise shared.

Another way to enhance confidentiality for subjects who provide illegal, deviant, or otherwise sensitive information is to obtain a Certificate of Confidentiality. Certificates of Confidentiality are special agreements between investigators and the government that are designed to protect subjects by

preventing a court-ordered subpoena from compelling the disclosure of identifying information. In the 1970s, Congress realized that people would be less than willing to participate in research involving sensitive issues, such as illegal drug use, unless their identifies were protected. The 1988 Public Health Service Act (301[d] 42 USC 242a) established the Certificates, which remain available to bona fide studies, whether or not they are funded or sponsored by the government (Sieber 1992). Certificates are granted on request when studies require such protection to protect subjects and complete research objectives (National Cancer Institute 1998). Although at least one court has upheld validity of such contracts, the prevailing view in the IRB community is that a sufficient test has not yet been conducted (Boruch, Dennis, and Cecil 1996; Kaltman and Isidor 2002; Torress 1984).

Congress has refused to extend to researchers blanket immunity from identifying subjects (Torress 1984). Although the law generally protects journalist-source, lawyer-client, doctor-patient, and some other communications, it does not protect researcher-subject communications, at least when it comes to serious crimes.[25] A notable example involved a sociologist who refused to disclose criminal information obtained in his research. A judge found him in contempt and jailed him for 159 days (Monaghan 1993a, 1993b). Legally distinct are situations in which a (corporate) body files civil suit and subpoenas data. Examples include tobacco and drug companies who seek documents to defend themselves against class action torts. So far in all cases where biomedical information was subpoenaed, courts have protected identifying information while holding the data available to discovery (Boruch, Dennis, and Cecil 1996; Holder 1986). Of course, the preceding discussion says nothing about mandatory reporting requirements for physician, nurse, and psychologist investigators (Nakdimen 1991; Steinberg et al. 1999). I assume few evaluators are so obliged.

There are still many other complex confidentiality issues that evaluators confront. One concerns focus groups, which are designed to elicit spontaneously reactive subject responses (Kruerger 1994). How can confidentiality be protected and maintained here? Do subjects truly appreciate that, in the excitement of a moment, they may reveal private or personal information to an entire group of peers? Another concern is proxy surveys, wherein evaluators ask one subject about another. Classic examples include husbands reporting information about their wives, surveying adult children about their aging parents, or teachers about their students. My view is that proxy surveys breech confidentiality and privacy imperatives (Oakes 2002), but there are

reasonable exceptions. Space constraints prevent additional discussion here, but more is needed.

THE LAST STEP

The last step in the education solution is to educate IRBs about our methods and risks they pose. Like the work on response-rate effects, subject compensation, and active/passive consent mentioned above, IRB education must be empirically driven and of the highest caliber. Speculation and anecdotes, although perhaps part of the process, will not be sufficient. To alter their ethically mandated conservative bias, IRBs can only rely on sound, unassailable science. High-quality data on the risks of low-risk studies are a must. Until then, IRBs must make decisions in light of hypothetical worst-case scenarios.

It is remarkable that evaluators (and all others) have largely overlooked this research gap and the opportunity to fill it. Sadly, the situation today is no different than in 1980, when turmoil ruled the day. Today's heated debates and discussions about IRB policy continue to suffer a dearth of empirical data.[26] There remain few rigorous studies of social research risks, IRB activities, IRB effectiveness, or the effects of IRB policies on research (Gray, Cooke, and Tannebaum 1978). Results from experimental designs would be most helpful, but careful systematic observational designs would be of use. When viewed as a social program, IRBs and related human subject protections offer many questions ripe for evaluation science (Elster 1992; Robertson 1982; Stanley and Guido 1996).

What questions need addressing? The list begins with: (a) What are the risks posed and literally experienced in social scientific investigations, as compared to biomedical evaluations? (b) Are IRBs in for-profit organizations as independent, objective, and protective as those in not-for-profit entities (e.g., universities) or the new commercial/independent IRBs? (c) How effective are informed consent procedures in community-trial and empowerment-evaluation designs? (d) How great is the need and effectiveness of ongoing IRB oversight? (e) What are the costs and benefits of a hypothetical formal mechanism to appeal IRB decisions? (f) To what extent are social science methodologies employed in biomedical research, and do settings modify the associated risks? (g) What is the optimal amount and form of compensation for repeated-measure surveys and focus group participants? (h) How effective are IRB training programs aimed at researchers and IRB members? and

(i) Do IRBs cause any harm by slowing otherwise safe and productive research?

In light of the ongoing conflict and stated OHRP interests, studies answering questions such as these would be a significant contribution to the entire research community and therefore (must become) eminently fundable (NIH 2002). Educating IRBs would eliminate any remaining systemic conflict and, most important, improve the protection of human research subjects. Selfishly, studies such as these would also elevate the place of evaluation science in the broad research community.

CONCLUSIONS

A motivating objective of evaluation science is to benefit individuals by improving social conditions (Rossi, Freeman, and Lipsey 1999). Even evaluations that reveal negative program effects are valuable because they (should) compel decision makers to adjust allocations. Human research subject protections go hand-in-hand with these goals. Although we may occasionally be frustrated by rules, policies, and seemingly inconsistent IRB decisions, we need to remember that just as helping people is central to our science, it is central to IRB oversight. Indeed, the IRB system did not spontaneously appear from the ether to frustrate researchers and create bureaucratic obstacles. The situation today is a direct consequence of many documented violations of very basic ethical standards. That many of these occurred in biomedical investigations only means that social scientists need to ensure such harms never befall their subjects.

Pursuant to policy recommendations (DHHS 1998; Ellis 1999; General Accounting Office [GAO] 1996), this article aimed to help social scientific evaluators better understand IRBs and thereby enhance the protection of research subjects. The main point was that IRBs are legitimate mediators of human subject research and that the answer to frustration lies in education for ourselves and IRBs—a peer education process. To that end I explained basic and more complex IRB issues and offered a critically important research agenda. In short, I have tried to guide evaluators *to* IRBs.

To everything discussed thus far, I add a final table of 15 tips (see Table 4) for social scientists hoping to improve their relationships with IRBs, better protect the people they seek to help in the first place, and enhance the public's view of and willingness to participate in evaluation research.

TABLE 4: Fifteen Tips for Improving Interactions With the Institutional Review Board (IRB)

Carefully plan the ethical aspects of your study from the very beginning—study the Belmont Report.
Attach to your IRB application a cover letter summarizing your study, with special attention to human subject interactions.
Examine university and Office of Human Research Protections (OHRP) Web sites for examples and specific directions.
If you have questions, telephone and talk with your IRB administrator.
Ask yourself if you would honestly want someone you love to participate in your study.
Work hard to ensure that recruitment materials yield equitable and noncoercive results.
Write consent forms at an eighth-grade reading level.
Overestimate risks and underestimate benefits.
Educate and debrief subjects on the nature, purpose, and findings of your study.
Establish procedures to delink identifying information from main data sets and sources.
Establish procedures to encrypt any and all identifying information and destroy it as soon as possible.
If you disagree with an IRB decision, read the regulations and then ask for an in-person meeting to discuss things.
Remember that research is not a right but a privilege and IRBs are peer review groups.
Educate your local IRB and then volunteer for it.
Never forget that IRBs did not spontaneously appear to frustrate scientists; they are a direct consequence of many documented violations of very basic ethical principles.

NOTES

1. This is to say nothing of ethically challenged research conducted by the U.S. Department of Defense on unconsenting and often unknowing military and civilian subjects, which involved mustard gas and lewisite; open-air testing of chemicals, bacteria, and viruses; radiation exposure; hallucinogens; and unproven vaccines (Committee on Veteran Affairs 1994)—or other secret Department of Energy sponsored experiments run between 1944 and 1974 that involved injecting hospitalized patients with plutonium, feeding radiation-laced breakfast cereal to institutionalized adolescents, exposing cancer patients to total-body irradiation, and irradiating the testicles of prisoners in state penitentiaries (ARCHE 1995).

2. Curran (1969) explained that prior to 1960, there was little law on medical research—no explicit regulations or detectable law suits. Prior to 1960, lawyers cautioned physicians that because medical experimentation could be seen as a conflict of interest, they were conducting research at their own legal risk. Despite such cautions, physician-researchers and their interest groups opposed any regulatory oversight (Moreno 1997; Curran 1969).

3. A very recent text (Amdur and Bankert 2002a) provides novel and comprehensive practical guidance to Institutional Review Boards (IRBs) on many contemporary issues, including social scientific protocols. The popularity of this text is rapidly growing among IRB members and bioethicists. But this text is directed at IRB members, not researchers who appear starved for understanding and relief.

4. American Evaluation Association (AEA) at www.eval.org/EvaluationDocuments/aeaprin6.html; American Association for Public Opinion Research (AAPOR) at www.aapor.

org/ethics/; American Sociological Association (ASA) at www.asanet.org/members/ecoderev.html; American Psychological Association (APA) at www.apa.org/ethics/code.html; and American Statistical Association (ASA) and www.tcnj.edu/~ethcstat/.

5. It seems that the only social scientist to regularly address IRB issues is Sieber (1982, 1984, 1992, 1998, 2001). But she has not been able to address every issue and, in any case, it is time for an update and tailored exposition.

6. A search for *human research subjects* or *ethics* produced 125,300 citations, with seemingly the same substantive outcome.

7. IRBs are specific to the United States, but other developed countries rely on similar bodies. Description, comparison, and contrasts between such arrangements merit careful attention but are beyond the scope here (see NBAC 2001b). However, as a rule of thumb, U.S. IRB regulations and the Belmont Report must serve as the baseline for all international research conducted by covered U.S. institutions.

8. These are illustrative and not necessarily from the University of Minnesota. Sadly, I believe most IRB members would convey these same sentiments.

9. Note that only 5 of the 11 Commission members were permitted to have conducted research with human subjects: There were 3 physicians and 2 psychologists. No practicing social scientists contributed (Gray 1982).

10. Respect for persons involves the recognition of personal dignity and autonomy and special protection for persons with diminished autonomy (informed consent). Beneficence entails obligations to protect people from harm by maximizing benefit and minimizing risk (risk/benefit analysis). Justice requires that benefits and burdens be distributed fairly (recruitment) (Penslar 1993).

11. Lawyers and courts have not only rejected First Amendment claims but in an ironic twist have also supported the requirement for equity in the selection of research subjects on grounds of the Fourteenth Amendment (Equal Protection). See Tropp (1982).

12. In February 1966, when Surgeon General Dr. William H. Stewart first issued orders that extramural National Institutes of Health (NIH) studies required an IRB review, attention was only directed at medical studies posing physical harm. By December of the same year, Stewart changed his policy and mandated review of social and behavioral research, too. One observer recalls that Stewart said something to the effect of,

> Well, sure, there are a few circumstances in which problems might arise with social research, too. Informed consent is always important and, of course, confidentiality matters when you're looking at behavior. Anyway, there aren't that many such studies. Let's just treat 'em all like biomedical stuff. (Pattullo 1984, 12)

13. There seems to be no systematic data on incidents of harm by simply asking survey questions. My minimal anecdotal research suggests that though rare, unfortunate events including suicide have occurred (see Oakes 2002).

14. In 1997, two Florida men, one an investigator for the state's health department, were convicted of leaking the names of 4,000 people who had tested positive for the human immunodeficiency virus (Wheeler 1999).

15. Although one report indicates that the concerns of social scientists are a priority of a new Health and Human Services advisory committee, only two social scientists sat on the 17-member panel (Brainard 2001).

16. All of the following are cited in the Federal Register (Vol. 65, p. 82462 [cited hereafter as 65 FR 82462]): A candidate for Congress nearly saw her campaign derailed when newspapers published the fact that she had sought psychiatric treatment after a suicide attempt. A 30-year FBI veteran was put on administrative leave when, without his permission, his pharmacy

released information about his treatment for depression. Consumer Reports found that 40% of insurers disclose personal health information to lenders, employers, or marketers without customer permission. A banker who also sat on a county health board gained access to patients' records and identified several people with cancer and called in their mortgages.

17. Most of the survey research conducted by the Census Bureau is considered exempt due to a different law, having to do with Federal statute protecting confidentiality: 15 CFR 27.101(b)(3)(ii).

18. Photographs and video are considered identifiers (Tropp 1982).

19. Some distinguished commentators suggest that the "and" in point (b) implies that most all survey research is beyond the scope of the IRB review. Shelton (1999), for example, noted that it is not enough that there be some hypothetically possible risk but that risks from disclosure must be readily significant and appreciable for research to be covered by an IRB. But Shelton discounted the ease with which links between databases can increase risk. It no longer takes much effort to merge databases from any number of sources and discover new information about a subject, placing them at risk. This is especially true when researchers recruit subjects from the same neighborhoods, clinics, or businesses—as evaluators often do. Participant protections seem maximized by placing less weight on the risks from disclosure and more on whether the data are identifiable. Although deemphasizing the requirement of "appreciable risks from disclosure" means that few health surveys will enjoy exemption status, this should have little effect.

20. The National Commission recommended that there should be an order of preference in the selection of groups of subjects: adults before children, competent individuals before incompetent individuals, and noninstitutionalized persons before institutionalized ones. In addition, the Commission recommended that IRBs consider the extent to which the proposed subject population is already burdened by poverty, illness, poor education, or chronic disabilities (Penslar 1993).

21. With respect to cultural sensitivity, the views of one anthropologist (Fluehr-Lobaan 2000) are worthy of paraphrase:

> Some scientists might argue that informed consent is a specialized Western ethical and cultural principle from which research outside the West is exempt. Others might say that primitive people are incapable of giving consent because they are an isolated group of, say, simple horticulturalists who could not understand the scientific purpose of genetic or social research or its ramifications. These arguments are misplaced: there is no human being or culture anywhere on earth that does not understand the difference between disease and health, life and death, or cultural survival and cultural extinction. An inability to obtain informed consent may mean that research cannot or should not take place. (P. B24)

However, the opposing thoughts of Newton (1990) are also compelling.

22. The ethics of and research on child-assent/parental-consent merits a separate article. It is directly related to consent in populations thought unable to give it, such as the cognitively impaired. Suffice it to say that the issue is controversial and evolving, especially with respect to nontherapeutic interventions and studies of illegal or immoral behavior. As a rule of thumb, studies greater than minimal risk must yield direct therapeutic benefit to the subject, and both parents/guardian and child/impaired subject must still consent.

23. Although not conclusive, some evidence suggest that this claim is incorrect. See Boruch, Dennis, and Cecil (1996).

24. These guidelines are consistent with those of AAPOR. Former AAPOR president, Stanley Presser, argued that a professional standard for the destruction of identifiers was ethically right and best for the survey researcher (Presser 1994).

25. Note that in recognizing that different acts evoke different social meanings, the Supreme Court stated in *Branzburg v. Hayes*, a landmark First Amendment case, that confidentiality competes with other societal values in the adjudication of crimes; through this analysis, the Court held that compelling a journalist to disclose direct observations of a crime before a grand jury did not violate the Constitution. An absolute scholarly research privilege, like absolute protection of journalists' sources, would therefore seem at least legally inappropriate (McLaughlin 1999).

26. The National Bioethics Advisory Commission (NBAC) wrote, "Deserving of more study, for example, are questions regarding the development of effective approaches for assessing cognitive capacity, for evaluating what participants want to know about research, and for determining how to ascertain best practices for seeking informed consent" (66 FR 45998).

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