

CHAPTER 14

Ethics and Values in Sociological Practice

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Sociological practice raises a set of ethical issues and values that differ somewhat for clinicians who conduct interventions and applied researchers who carry out assessments and evaluations of programs or analyze policies. This chapter will review the history of human research protections, examine portions of Title 45, Part 46 of the *Code of Federal Regulations* referred to as *45 CFR 46* or the "Common Rule" that governs federally funded research, and discuss issues confronting sociological practitioners in obtaining approval for research activities.

A Brief History of Human Research Protection

The issue of the ethical responsibilities of researchers emerged after World War II with the realization that Nazi physicians had conducted experiments in concentration and prisoner of war camps. The physicians were brought to trial and the verdicts against them included ten points that became known as the Nuremberg Code. The points included obtaining voluntary consent to participate in experiments, avoiding all unnecessary physical and mental suffering and injury, the ability of a person to end their participation at any time and the willingness of scientists to terminate the experiment at any stage if its continuation will result in harm to the participant.

In February 1966, US Surgeon General William Stewart issued a statement on clinical research and investigations involving human beings (see Schrag, 2009). It required that in order to receive a Public Health Service (PHS)

grant, all studies, including those in the behavioral and social sciences would have to undergo the same vetting as medical experiments. This meant prior review by institutional associates to assure an independent determination of the protection of the rights and welfare of the participants. As a result universities began to establish what are now known as Institutional Review Boards (IRBs).

While the original focus had been medical and clinical research, the social and behavioral sciences were included because of concerns over invasions of privacy. In 1965 Congressman Cornelius Gallagher (D-NJ) and a House Government Operations subcommittee held hearings on the use of psychological tests such as the Minnesota Multiphasic Personality Inventory (the MMPI) on federal employees and job applicants. During the hearings a witness mentioned that some mental health research sponsored by the PHS contained questions of a personal or intimate nature, but that participation was entirely voluntary and that invasion of privacy did not arise. Gallagher and three other Congressmen requested that the PHS make sure that protecting personal privacy was a paramount concern. In turn, James Shannon, director of the National Institutes of Health assured the Congressmen that this was the policy and later stated "It's not the scientist who puts the needle in the bloodstream who causes trouble. It's the behavioral scientist who probes into the sex life of an insecure person who really raises hell." (Schrag, 2009: 3).

A 1972 article by reporter Jean Heller about the Tuskegee Syphilis Experiment propelled the protection of human research participants onto the front pages of most major newspapers. In 1932 the PHS and the Tuskegee Institute enrolled 400 poor black men in a longitudinal study of syphilis. The men were not told they had syphilis, but were given free medical exams, free meals and free burial insurance. At the time, no proven treatment existed, but by 1947 penicillin was recognized as being effective. Nevertheless the men were not treated, and as a result many of their wives and children were infected (Tuskegee, 2002). The Department of Health, Education and Welfare (DHEW) appointed the Tuskegee Syphilis Study Ad Hoc Panel to review the study as well as the department's existing policies and procedures for the protection of human subjects. The panel recommended that Congress establish a permanent body with the authority to regulate all federally supported research involving human subjects (Advisory Committee on Human Radiation Experiments (ACHRE), 1995).

The US Senate held hearings in February 1973 on the issue and identified a wide range of abuses in medical research and the field of human experimentation, which included psychology and by extension, other social and behavior sciences. At the end of May 1974, DHEW published regulations for the use of human subjects requiring the formation of what an Institutional Review Board (IRB) to approve all research proposals before they were submitted to DHEW for funding consideration. These committees were to review, among

other things, the safety (risks and potential benefits) of the proposed research and the adequacy of the informed consent obtained from each subject prior to participation in the research. Two months later, in July 1974, the National Research Act was passed, officially giving DHEW the authority to establish regulations in this area (ACHRE, 1995). The law specifically limited the scope to biomedical and behavioral research.

The National Research Act also established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. Congress charged the National Commission with the task of identifying the basic ethical principles that affect the decision to use, or to not use, human research subjects. The Commission was to then develop guidelines to assure that research involving human subjects would adhere to the ethical principles, that is, it was asked to link norms with values. Specifically, the Commission was to address issues that had been raised in the Tuskegee Syphilis Experiment: informed consent, assessment of risks and benefits, and selection of subjects. The eleven member Commission consisted of three physicians, three attorneys, a bio-ethicist, a Christian ethicist, a behavioral-biologist, a physiological-psychologist and the president of the National Council of Negro Women, Inc. Noticeably missing were members representing the main line social science research disciplines such as social and clinical psychology, sociology, and anthropology. In February 1976, the Commission held a four-day meeting at the Smithsonian Institution's Belmont Conference Center and its 1979 final statement, "Ethical Principles and Guidelines for the Protection of Human Subjects of Research," would be known as *The Belmont Report* (1979).

The Belmont Report begins by distinguishing between the practice of accepted therapy and biomedical/behavioral research. "Practice" was defined as interventions designed solely to enhance the well being of an individual patient or client and that have a reasonable expectation of success. "Research" involved activities intended to test hypotheses, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge. The Report recognized that the boundary between research and practice is often blurred because both may occur together, for example when research is designed to evaluate a therapy. Furthermore, while a clinician may develop new or untested procedures that could be considered experimental, this did not automatically place it in the category of research. Rather, the Commission expected that at an early stage such experiments would be made the object of formal research in order to determine whether they are safe and effective. The Report concluded that if an activity included any element of research, that activity should undergo review for the protection of human subjects.

The Commission declined to make any policy determination regarding the research problems related to social experimentation because such problems may differ sub-

stantially from those of biomedical and behavioral research. The Commission, naïvely it turns out, stated that such problems ought to be addressed by one of its successor bodies. As a result all research efforts—biomedical, behavioral, and social—were essentially treated alike when it came to writing legislation and regulations. But by the time the Commission was finishing its report; two social science research studies had become highly controversial for their methods and findings, raising new ethical issues regarding social and behavioral research.

Stanley Milgram's (1974) *Obedience to Authority* investigated the conditions under which naïve individuals would follow the direction of an authority figure even when it was apparent that they would injure another person. Milgram deceived subjects into believing they were administering ever increasing electrical shocks to a learner every time he gave an incorrect answer. The last ten shock levels were clearly marked as "extreme intensity shock," "danger: severe shock" and finally between 435 and 450 volts as "X X X." It is obvious from Milgram's pictures and film that many subjects exhibited signs of intense stress as they decided whether to administer the next higher level of shock or stand up to authority and refuse to continue. At one point Milgram likened the stress to the temporary scare one experiences riding a roller coaster. Milgram debriefed all subjects after the experiment was over and conducted a follow-up survey to identify any long-term effects. The survey revealed that only one percent reported feeling sorry or very sorry to have participated in the experiment. But critics claimed that the realization of what they had done had a lasting impact on the subject's own personality and that the subjects told Milgram what they thought he wanted to hear during the debriefing and in the follow-up survey.

Around the same time, in the field research reported in *Tearoom Trade*, Laud Humphrey (1975) observed homosexual encounters at a men's restroom in a public park. A few men at the restroom questioned why he was hanging around, and advised him to function as a "watch queen," that is a voyeur who also served to warn of any approaching police. To gain more information about some of the men, he copied their license plates and was able to obtain home addresses with the assistance of someone in the local police department. He then included 50 of them as a comparison group in an ongoing survey he was conducting of men's social health. He interviewed them in their homes, explaining that they had been randomly chosen to participate in the survey. But none of those interviewed knew the true reason they were selected or that he had previously observed them as the watch queen at the restroom. In his dissertation and subsequent publications, Humphreys hid the identity of the men he observed and interviewed, knowing the consequences if they were "outed." He later burned all identifying materials. Nevertheless, some claim that the level of detail was such that a few individuals could be identified.

To accomplish its main task, the Commission looked at writings and discussions that had taken place to date and asked, “What are the basic ethical principles that are used to judge the ethics of human subject research?” *The Belmont Report* identified three principals relevant to the ethics of research involving human subjects: respect of persons, beneficence and justice. The principle of *respect for persons* concerned the moral requirements to acknowledge the autonomy of individuals to make informed decisions and to protect those with diminished autonomy, specifically children, and prisoners. The principle of *beneficence* was the obligation not to harm, which reflected the Hippocratic Oath. It also considered the consequences of action by focusing on maximizing possible benefits while minimizing possible harms. The third principle, *justice*, asked, “Who ought to receive the benefits of research and bear its burdens?” It required that the selection of research subjects be fair and directly related to the problem being studied. Subjects should not be recruited on the basis of convenience or manipulability. Further, the resulting therapeutic devices and treatments should not be provided to only those who can afford them and denied to those who had participated in the research.

The Commission then applied the three principles to the three major charges set by Congress: informed consent, assessment of risks and benefits and the selection of subjects. While these already existed in semi formal research practices, the Commission took what might be called scientific folkways and developed an ethics of responsibility by identifying a corresponding moral requirement. *The Belmont Report* retrospectively provided a rationale for title 45, part 46 of the Code of Federal Regulations (45 CFR 46) that was published just before creation of the Commission. The Report became the basic document that underpinned the implementation and interpretation of the federal regulations as well as future amendments.

The Common Rule—Review Categories and Waivers

In 1981 the President’s Commission for the Study of Ethical Principles and Guidelines for the Protection of Human Subjects of Biomedical and Behavioral Research recommend that all federal agencies adopt a “Common Rule” for research protections. By 1991, 16 federal agencies had adopted 45 CFR 46 as governing the research they sponsored. Of interest to most social and behavioral clinicians and researchers are the definition of research, the categories for exemption from review and expedited review, as well as conditions for waiving consent and documentation of consent.

Research is defined as a systematic investigation, including the development, testing and evaluation of hypotheses designed to develop or contribute to generalizable knowledge. In addition some demonstration and service programs may include research activities. This means that, if supported by federal funds, sociological practitioners involved with the development, assessment or evaluation of various programs and groups are subject to an Institutional Review Board (IRB). An IRB is the administrative body of a university, hospital or research institution established to protect the rights and welfare of subjects recruited to participate in biomedical or behavioral research. It has the authority to approve, require modifications in, or disapprove all research activities as specified by both federal regulations and the institution's own research policies. (Office of Human Research Protections (OHRP) 1993). Private foundations that fund programs and initiatives involving assessment or evaluation generally require IRB review and many universities and hospitals require that all researchers submit their proposals for IRB review.

Some activities conducted by sociological practitioners such as political polling, market research and program evaluation may not fall under the definition of research in *45 CFR 46*. In most cases the results will only be used by the sponsoring entity and are not intended for external reporting. Similar activities conducted by journalists and the media are not covered because they are not federally funded and their findings contribute to public knowledge of events and issues.

45 CFR 46 contains provisions that exempt some activities from review. These include (a) research conducted in established or commonly accepted educational settings, involving normal educational practices, (b) research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior as long as the subjects cannot be identified and any disclosure of their responses outside the research could not reasonably place them at risk of criminal or civic liability or damage their financial standing, employability or reputation, (c) 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 previous investigator in such a manner that subjects cannot be identified, (d) 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 public benefit or service programs, and (e) taste and food quality evaluation and consumer acceptance studies.

What Does this Mean for the Practicing Sociologist?

A prudent sociological practitioner employed by or under contract with a university, health care facility or social service agency should submit a research

application or proposal to an appropriate IRB requesting recognition of exempt status. This protects both the practitioner and the institution by assuring that human research protections are followed although the activities will not be monitored by the IRB.

Research involving no more than minimal risk may undergo an expedited rather than full review. 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. The following types of research are eligible for expedited review if they involve no more than minimal risk:

- Research involving data, documents or records that have previously been collected for either research or non-research purposes or will be collected solely for non-research purposes,
- Collection of data from voice, video, digital or image recordings already made for research purposes,
- Research on individual or group characteristics, attitudes or behavior including interpersonal relationships and cultural beliefs or practices,
- Research employing methods commonly used in social, behavioral, epidemiological, health services and educational research such as survey, interview, oral history, participant observation, ethnography, focus group, program evaluation, human factors evaluation or quality assurance methods.

While some of the above listed research may already be exempt, it is the responsibility of the researcher to check with the appropriate IRB on the correct review category for their research and to explain how the proposed research would not exceed minimal risks.

Researchers may also request a waiver from the requirement to obtain informed consent. Research conducted by or for state or local government officials to study, evaluate or examine public benefits or service programs may be eligible for a waiver if the research could not practicably be carried out without the waiver. But more generally, informed consent may be waived if the research involved no more than minimal risk, the waiver will not adversely affect the rights and welfare of the subjects, the research could not practicably be carried out without the waiver and subjects will be provided with pertinent information about the research after participation whenever appropriate.

In general IRBs are reluctant to waive informed consent for subjects who are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons. However, some IRBs have waived parental consent

or permission for a minor child to participate in research as well as the assent of the child. For example Youth Risk Behavior Surveys (YRBS) are administered to middle and high school students about the use of alcohol, tobacco and other drugs or dietary and sexual behaviors. The survey is entirely anonymous, standardized, and administered nationwide through state and local public health agencies. The survey design selects classrooms not individual students to participate. Each local school district approves the survey, the decision to participate in it, and the mechanism for active or passive parental consent. The IRB at the Centers for Disease Control, which oversees and partially funds these national surveys, determined that the surveys were not research but rather part of public health practice. Therefore IRB review and approval was unnecessary, and by extension individual or guardian informed consent under the Common Rule was likely unnecessary (Hodge 2004:44).

Nevertheless some state and local health departments and their university partners that conduct the YRBS require that all federally funded research be locally reviewed. This complicates matters. For instance, one university IRB denied approval because parental consent was passive. In passive consent a form and detailed information about the study was distributed to parents and if the parents did not return the form, the parents were deemed to have granted passive consent. Some parents will send the form back indicating they do not want their child to participate, and those children will not be included in the study or given the survey.

The request for a waiver from documented informed consent began by pointing out that the survey was being carried out on behalf of state or local public health officials. It then argued that the study could not be practicably carried out using active consent. The purpose of the study was to identify and assess risky behavior among students and having a highly biased sample of only those children whose parents returned a signed consent form would not suffice. In addition the children received an assent form with the survey that they did not have to sign. The assent form clearly stated that they did not have to complete the survey and should quietly sit at their desks until time was up. The questionnaire was anonymous, the completed surveys and data would be securely kept by the university based survey research center, and all reports would contain aggregate data. The rights and welfare of the children were protected through the sampling procedure of classrooms rather than individuals and the anonymity of the surveys. Finally the children were told that if, after the survey, they had any questions or problems they could contact a trusted guidance counselor in their school. After some negotiation with the university IRB the waiver was approved.

Documented informed consent may be waived in cases where the data is collected and recorded anonymously and subjects would be better protected without the existence of a signed document. Waivers may also be granted for

secondary data about human subjects where no possible personal identifiers are transferred to the researcher. Finally in some cultures and organizations individuals are wary of signing a consent form but are willing to verbally consent to an interview, survey or observation. Again it is the responsibility of the researcher to fully document the waiver request by addressing each of the four waiver criteria whether they seem to apply or not.

Obtaining Approval for Research Activities

All researchers and practitioners should act ethically and adhere to the principles and regulations covering human research protections, but problems arise in dealing with the system. A good deal of *45 CFR 46* pertains to the establishment and functioning of Institutional Review Boards. As we have discussed, the system is decentralized and the government has, in effect, entrusted human research protections to individual educational, health and research institutions (Seligson, 2008). The idea was to avoid a federal level review board that would not be able to handle the hundreds of thousands of proposals and could not take into account local research conditions and contexts. Decentralized review had developed during the middle of the twentieth century when organizations sponsoring medical research created scientific advisory panels to monitor the hazards of clinical trials. The scientific community was seen as the carrier of informal morality, or research mores, which rested on networks of researchers sharing a sense of collective responsibility. Their expertise and investigation of common questions enabled them to provide informal oversight and evaluate potential hazards (Halpern, 2004).

Decentralized review has its drawbacks, especially if an appeals procedure is absent. In modern society most governmentally established bodies have limited powers of decision making for which they can be held accountable (Nobles and Schiff, 2002), but each IRB is an autonomous entity and is not required to follow precedent. Each case is decided on how well it meets the seven criteria listed at *45 CFR 46.111*. This means that an IRB may reach different decisions in what appear to be similar circumstances. Furthermore, research approved by one IRB may not be approved by another. While IRBs may be accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP) for having and following standard policies and procedures, this does not replace an appeals process in which decisions can be reviewed and overturned by a higher level administrator, independent mediator, or a law court. Researchers do not enjoy a right of appeal of IRB decisions (Perlstadt, 2004). An appeal of an IRB decision cannot be made to an official of the institution such as a Vice President for Research. Rather the appeal is to the chair of that IRB who may

then ask other members of the IRB to review or reconsider the decision. This means a researcher who strongly disagrees with an IRB decision must find a way to finesse the system.

In one case a university researcher working with a community based organization received IRB approval for an observational study of tobacco sales to minors (Malone, Yerger *et al*, 2007). The study would include mapping all convenience and liquor stores in the community, a survey of tobacco advertising in the community, observed smoking activity of minors in public places and store sales practices including single cigarette sales. No individuals, stores or sales clerks would be identifiable from the data and findings would be reported in the aggregate. After a short time, the community based organization wanted to have minors attempt to purchase single cigarettes. This modification was submitted to the IRB which rejected it, arguing that the minors were being asked to commit an illegal act and that trying to buy single cigarettes constituted entrapment of store personnel.

The decision was appealed and the researcher submitted documents including a grant of immunity signed by the local district attorney, a section of the state penal code that buying a single cigarette was not illegal, a written opinion from the state attorney general that such research activity was not entrapment, and citations to other studies using identical procedures. The IRB turned down the appeal on the grounds that the anticipated benefits of the study did not justify the risks. Perhaps it believed that the modification had become an experimental intervention involving deception of clerks and was no longer a research project that it could approve and monitor. In response the community based organization broke off from the research project and carried out the activities independently as a community action project, knowing that any results could not be published or reported as findings of the university based research project. It could, however, post its findings on its own website and present them at city or county council meetings on tobacco control.

In another case, one component of a federal program required the provision and evaluation of mental health services to teen parents who were referred to the agency by child protective services for child abuse or neglect. The mental health agency used a standardized and verified intake and exit instrument that could be used to assess the success of treatment. The evaluator made arrangements to obtain de-identified data on the cases that included only summary measures of attitudinal and behavioral change. Because these were mental health records, the IRB insisted that the evaluator obtain documented informed consent from each parent. But the research could not practicably be carried out without the waiver because if the evaluator were to contact the families to obtain consent it would mean their confidentiality, and from the evaluators perspective their anonymity had been compromised. Further, parents were given a booklet at the time

of their intake containing the state law governing mental health services that informed them that their cases could be used for research or evaluative purposes provided that their identities were protected. When the IRB rejected the appeal, the evaluator drafted a report to the sponsoring federal agency explaining the above situation, inserted a blank page and stated that as a result, the following blank page was the total evaluation report for this component of the program. The draft was sent to the chair of the IRB who quickly set up an appointment and negotiated a procedure to access the data without requiring the documented informed consent.

Of greater interests to sociological practitioners is when a project starts out as non-research but slowly evolves into research. *The Belmont Report* recognized that the boundary between practice and research is often blurred because both may occur together or that research may evolve out of non-research activities. The Report believed that in such situations, the activities would become research and adhere to the basic principles. However, 45 *CFR* 46.119 only deals with this issue in terms of research that was undertaken without the intention of involving human subjects. In such circumstances, the research is first reviewed and approved by an IRB followed by a certification submitted by the institution to the federal department or agency that can grant final approval for the proposed change. This appears to be a rather high hurdle and one that might be appropriate for drug trials moving from laboratory or animal testing to human subjects.

Activities carried out by sociological practitioners usually begin with individuals or groups as human clients, not as human subjects. At some point the practitioner realizes that the activities and results should be systematically recorded as they could contribute to generalizable knowledge and be treated as research. The prudent sociological practitioner should be following the code of ethics of the Association of Applied and Clinical Sociologists (AACS) or the American Sociological Association (ASA). The AACS principle on responsibility notes that in their practice, sociological practitioners bear a heavy responsibility because their recommendations and professional actions may alter the lives of others. Sociological practitioners recognize that they must not do harm to clients or research subjects. In addition sociological practitioners are alert to personal, social, organizational, financial, and political situations or pressures that might lead to the misuse of their influence.

Concerning unanticipated research opportunities, the ASA's ethical standards state that if, during the course of teaching, practice, service, or non-professional activities, a sociologist decides to undertake research that was not previously anticipated, steps should be taken to announce this intention and to ensure that the research can be undertaken consonant with ethical principles, especially those relating to confidentiality and informed consent. The sociologist should seek the approval of an Institutional Review Board or, in the absence of

such review processes, another authoritative body with expertise on the ethics of research.

If some aspect of research has already been started such as recruiting subjects or data collection, the practitioner-turned-researcher now has the tricky task of applying for retrospective approval. Clearly the regulations call for review prior to starting a study in order to protect participants, and the very concept of retrospective review is considered anathema. Almost all university based IRBs explicitly state that they do not have the option of granting retroactive approval after research is completed, and most professional journals state that they will not publish manuscripts that lack prior IRB approval.

Michigan State University's IRB offers a training program that features a series of scenarios that deal with the problem of emerging or unanticipated research (Vasilenko, 2007). The scenarios state: "You are the IRB Administrator and must decide if the following research needs to be reviewed by the IRB." Three scenarios are presented and discussed below.

In the first scenario, a Foundation contracts with a faculty member to do an evaluation of its teen pregnancy prevention programs, which include interviews with grant recipients and teen clients. The evaluation report will (a) be given only to the Foundation or (b) the Foundation has given the faculty member the right to publish any interesting data. Here the IRB administrator will probably decide that the project is exempt if the report is to be given only to the Foundation for its internal purposes (a), but that if permission has been granted to publish (b), an expedited or full review may be necessary depending on the nature of the questions asked of the teen clients who are considered doubly vulnerable as minors and possibly pregnant females.

In the second scenario a professor is subcontracted from another institution to perform an analysis on de-identified data. The professor is paid merely to provide statistical analysis and a statistical report to the investigator from the other university, but (a) is not to be a co-investigator or co-author, or (b) will be listed as a co-author on papers. In this case one assumes that the collection of the de-identified data was previously reviewed and approved. The preparation of a report on de-identified secondary data would not require review (a). The request to include the subcontracted professor as a co-author (b) could be exempted under the subcontracting institution's IRB approval yet require an expedited review at the subcontracted professor's home institution.

In the third scenario a teacher developed and used a novel approach to teaching science to elementary students. After three years, she has compared students' knowledge and performance (using students' work and grades) and finds the new approach is much superior. She wishes to present her method and data to a national teachers' convention. Clearly the teacher began this project for the benefit of her own students to improve teaching techniques and learning skills

that would be exempt under *45 CFR 46*. It is her intent to present her findings at a national teachers' conference that apparently triggered the submission for IRB review. On the surface, this appears to be a request for retroactive approval and the IRB administrator could recommend that the IRB reject the proposal without any review. The teacher should have realized early on that, certainly by the end of the first year, the results were presentable or publishable and requested a review. When practice activities have evolved into research, Tufts University, for example, recommends that the research be put on hold and an application submitted to the IRB. By coming to the IRB "as soon as you realize that you have made the mistake of not getting IRB approval in advance, you may be able to salvage some of your project" (Tufts, 2005). Often the cost of retrospective approval is the destruction of all data collected up to the point of approval.

Another issue facing the teacher in this scenario is finding an appropriate entity to review her research proposal. In general, school districts do not have formal IRBs, but they have committees that review and approve research. In fact IRB is a generic term used by federal agencies to refer to a group whose function is to review research to assure the protection of the rights and welfare of the human subjects (FDA, 2008). Although not the case in this scenario, if federal support is involved, such an entity is required to follow federal regulations.

Similarly, independent sociological practitioners should try to find an IRB to review their proposal if they are being funded in some degree by federal funds or intend to publish their findings. Besides universities and hospitals, the Association for the Accreditation of Human Research Protection Programs (AAHRPP) accredits commercial and independent IRBs that provide reviews for a fee. But many specialize in biomedical clinical trials, so it is important to find a commercial or independent IRB that has experience in social and behavioral research.

Lessons Learned

The last half of the twentieth century has witnessed the emergence of research ethics. The basic principle of beneficence, or do no harm, was extended from the realm of practice to the realm of research. Compared to practice, research imposes a rather impersonal and systematic relationship between investigator and subject. Therefore the principles of respect for person or individual autonomy and justice or being treated fairly and uniformly were added. Sociological practitioners must learn to deal with the boundary between practice and research.

Research ethics are reinforced through a decentralized system based at institutions providing administrative support and facilities for researchers. Each IRB interprets and enforces the federal regulations, which leads to inconsistencies

within and across IRBs. Since the IRB system reviews each proposal on its own merits, researchers perceive the decision as a private trouble requiring a private solution (Mills, 1959) that they must individually deal with if they wish to carry out and publish their research. They must learn to navigate and work the system. Unfortunately, training and tutorials for human research protection concentrate on exemplars of research misconduct that led to the development of research ethics, and the key requirements of documented informed consent, protection of vulnerable populations, and fairness in recruitment of subjects. What is largely omitted from trainings and tutorials are the provisions for waivers from these requirements and how to build a case for those waivers.

It is therefore necessary from the start for sociological practitioners to properly identify the nature of their research and its potential risks in order to apply for an appropriate review whether exempt, expedited or full. Since IRB members will interpret the regulations somewhat differently and take into account local research conditions and contexts, researchers should be prepared for requests to revise and resubmit their proposal. Usually this involves rewording the informed consent document or adding details on how the data will be securely maintained to protect confidentiality. But occasionally a proposal will be rejected for reasons that can be appealed through a waiver. The regulations are fairly clear on the four grounds for requesting a waiver and the researcher should address each of them in their appeal whether they seem to apply or not.

More problematic, however, is when a sociological practitioner realizes that a project not previously regarded as research now has research potential. The regulations at *45 CFR 46.119* dealing with research undertaken without the intention of involving human subjects appear to be based on biomedical and pharmaceutical research. They do not address situations that arise in social and behavioral research or the question of research that may evolve out of non-research activities. The reluctance of IRBs to consider retrospective review is understandable, but nevertheless some IRBs have done it. The best advice for a sociological practitioner at the point where the project is perceived to be researchable is to temporarily suspend all activities that could be construed as research and apply to an IRB for review. It helps if the practitioner already has a working relationship or at least contacts with an IRB. Both practice and research ethics demand the protection of clients and subjects.

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