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Behavioral and Social Science Research

Ethical issues in the conduct of behavioral and social science research with human participants involve considerations that are as diverse as the range of disciplines and fields that constitute these sciences. The methods, study populations, and issues being examined in studying behavioral and social processes all come into play in designing and implementing ethically sound research. This chapter provides an overview of the history of ethical considerations in the conduct of behavioral and social science research; addresses underlying ethical considerations that animate these fields of inquiry; unpacks the complexity of making ethical determinations, especially in the context of challenging circumstances, study populations, or methods; and raises issues—some unresolved—that merit consideration in planning for and reviewing research.

For all fields of human research, ethical determinations about the rights and interests of human research participants are an integral part of the research enterprise. Behavioral and social scientists undertaking research are informed by professional codes of ethics,[1–4] formal guidance enunciated in the Belmont Report,[5] and the Department of Health and Human Service's (DHHS) Policy for Protection of Human Research Subjects (45 CFR 46).[6] In the context of such guidance, scientists planning and implementing studies must make judgments about research participants, and thus need to apply ethical principles and rules responsibly to real-life circumstances in advance of and during the ongoing research process. This chapter examines how assessments about risk, harm, and benefit; confidentiality and privacy; disclosure and the processes of informed consent unfold in behavioral and social science research in relation to the substance of the study, the target population, and the specifics of the research method and design.

The social and behavioral sciences refer to a broad rubric of disciplinary and interdisciplinary fields dedicated to the scientific study of behavioral and social phenomena. Permeable at its boundaries, the term embraces fields ranging from anthropology, economics, political science, psychology, and sociology to linguistics, geography, demography, sociolegal studies, and education research, among others. Some disciplines like psychology have produced disciplinary subfields such as cognitive psychology or developmental psychology that also are quite interdisciplinary. Other fields, such as neuroscience, have interacted to create new arenas of scientific discovery and explanation. The richness and complexity of the behavioral and social sciences, the interdisciplinary synergism across these fields, and their growing interaction with the biological sciences can be seen in the conceptual framework used in volumes as early as the 1988 National Research Council report, *The Behavioral and Social Sciences,*[7] and more recently in the 2001 *International Encyclopedia of the Social & Behavioral Sciences.*[8]

In terms of health-related research, the Office of Behavioral and Social Sciences Research (OBSSR) at the National Institutes of Health (NIH) similarly conceives of behavioral and social science research to be a "large, multifaceted field" that is "not restricted to a set of disciplines or methodological approaches."[9] The OBSSR statement emphasizes the breadth of methodological approaches in these sciences, including surveys and questionnaires, interviews, randomized clinical trials, direct observation, physiological manipulations and recordings, descriptive methods, laboratory and field experiments, standardized tests, economic analyses, statistical modeling, ethnography, and evaluation. All of these methods come into play in behavioral and social science research on

health—whether it is in the context of fundamental studies designed to further understanding of behavioral or social functioning or in the context of clinical research designed to predict or influence health outcomes, risks, or protective factors. Indeed, it is the methodology, rather than the specific field or purpose of the study, that tends to signal ethical issues worthy of attention.

The literature on ethical considerations in behavioral and social science research involving human participants focuses on the shared methods and complementary interests that cut across these fields. In work that was published during the same period that the Belmont Report and the federal regulations were issued, the emphasis was on methods, ethical concepts, and the newly emerging federal role in human research regulation. For example, chapters in the 1979 volume *Federal Regulations: Ethical Issues and Social Research,*[10] edited by Wax and Cassell for the American Association for the Advancement of Science Selected Symposium Series, addressed the complex ethical issues involved in qualitative as well as quantitative research. Similarly, contributions in the 1982 volume *Ethical Issues in Social Research,*[11] edited by Beauchamp, Faden, Wallace, and Walters, or in the two 1982 volumes edited by Sieber under the overarching title *The Ethics of Social Research*[12,13] focused on how ethical issues present themselves in the context of different research methods and examined key concepts such as benefit and harm, deception and consent, and privacy and confidentiality. More than 20 years later, in 2003, the National Research Council report *Protecting Participants and Facilitating Social and Behavioral Sciences Research*[14] also emphasized the link between research methods and key ethical concepts.

Emergence of Ethical Considerations

Ethical considerations in behavioral and social science research became an explicit topic of attention during the 1960s and 1970s. During this period, four types of activities emerged that over time intersected in terms of both substantive issues and networks of behavioral and social scientists working in these domains. Each contributed to heightened interest in research ethics. First, there was the emergence of a subfield of research (largely located within social psychology) giving systematic attention to the study of behavioral and social science research as a social process worthy of investigation. Second, researchers and scientific societies in behavioral and social science fields began focusing on the ethical practices and the ethical responsibility of researchers to human research participants. Some high-profile studies brought attention to these issues. Third, the federal government, largely in the context of biomedical research, but also including behavioral and social science research, turned to addressing the regulation of research with humans. Fourth, and not unrelated, interest in the regulation and ethics of research as well as the establishment of formal mechanisms stimulated some social science research addressed to these issues.

Social Psychology of Research

The social psychology of research involves examining the dynamics of research as a social process and the factors that could affect or bias results.[15] Research that commenced in the 1960s focused on the unintentional effects on research participants' responses of the investigators' knowledge of the hypotheses and experimental conditions (i.e., expectancy effects),[16] the impact of the nature of the information (e.g., the form or the wording of language) on outcomes,[17] the influence on results of simulated behaviors (e.g., role-playing behaviors of shorter or longer duration), and even whether volunteering or assumptions about the likelihood of deception (irrespective of ethical considerations) may reduce research participants' level of engagement with the research questions or tasks.[18] The desire of research participants to help, the social influence exerted in the situation, perceptions of the research participants and the researcher regarding socially appropriate responses,[19] participants' concerns about negative evaluations (i.e., not being a sufficiently "good" participant),[20] and the demand characteristics of the research situation are some of the factors that interested behavioral and social scientists because of their possible consequences for the validity of research.[21,22] Although most of this research focused on laboratory experiments (the context of much social psychological research), the questions being asked were germane to both fieldwork and social surveys. In addition, although this arena of research was directed to understanding the research enterprise and what contributes to, or erodes, its validity, the social processes being studied were quite central to ethical considerations (e.g., the amount of information disclosed to human participants and the social influence of research situations on participants' autonomous behavior).

Heightened Attention to Ethical Considerations

At about this same time, another strand of research in the behavioral and social sciences was directly addressing topics related to human values (e.g., conformity, obedience, stereotypes).[23,24] This work sought to better understand the impact of social situations, influences, and norms on human behavior using compelling research designs and tools. The visibility of such studies and the broader attention in this post–World War II era to the treatment of participants in research also led scientific associations, including professional societies in the social and behavioral sciences, to address ethical considerations in the conduct of research.

High-Profile Research

Much of the debate that unfolded about human research ethics in the behavioral and social sciences had its roots in notable work done in this period. A number of substantive studies raised questions about the appropriateness of the research procedures from the vantage point of the research participants. Although raising ethical questions about a study is distinct from judging a study to be ethically questionable, these two responses were frequently confounded. In many respects, the several studies that were particularly high profile were exemplars of a genre of behavioral and social science research of that time. Three studies—cutting across laboratory and field contexts—are most highly cited for leading those in the behavioral and social sciences to explore what constitutes viable ethical practices in their research and the conditions and criteria that should be applied in making such determinations.[25,26]

In the 1960s, experimental studies of obedience undertaken by Milgram involved research participants "believing" that they were administering painful shocks to others in the context of

memory research. In reality, no shocks were being administered at all, despite participants being told that they were causing painful consequences to others.[27,28] The actual purpose of Milgram's research was to understand compliance with authority figures under varying conditions and to identify the factors that engendered resistance. The artificially constructed experimental situation encouraged participants to comply with authoritative instructions and continue to administer what they believed were painful shocks.

The scientific and social significance of Milgram's findings—that is, the propensity in certain situations for persons to obey authorities and override their sense of right and wrong—is generally acknowledged. Nevertheless, both the stress effects on participants of such compliance (resulting from "inflicted insights"[29]) and the deceptive scenario that placed them in this position, spawned significant discussion and debate in the research community, including by Milgram himself.[30–33] In many respects, Milgram was ahead of his time in explicitly addressing investigator's responsibilities to research participants. In his 1961 grant proposal to the National Science Foundation, for example, Milgram emphasized debriefing to put subjects at ease and to assure them of the adequacy of their performance. Conducting follow-up studies, he is credited with the first use of postexperimental procedures.[23] Although these studies showed that the vast majority of participants valued being in the study and only a few wished they had opted out, controversy continued to surround this research.

The 1971 prison simulation study by Zimbardo and associates[34,35] also framed ethical questions that engaged the attention of the research community.[26,36] Although there was no deception in this research, the long-term simulation of the role of prisoners or guards produced physical and psychological aggressive behaviors in "guards" and submissive behaviors in "prisoners." Participants became emotionally involved in their roles, leading to the experiment being terminated by the principal investigator because of concerns about psychological consequences.[35] Zimbardo's attention to research participant stress and the fact that he ended the study after six days are evidence of the care taken in the execution of this research. Though follow-up work identified no lasting adverse effects and yielded self-reports of benefits to participants, the study highlighted the larger ethical question of simulating behaviors that *could* induce sustained identity stress and potential psychological harm. How to weigh the potential risk of more than transitory stress in relation to the benefits of this form of research was, however, less a point of conversation than the behaviors that this simulation evoked.

The third inquiry conducted by Humphreys from 1965 to 1968 used participant observation and interview methods to study men who engaged in impersonal acts of fellatio in public restrooms (the "tearoom trade").[37] The research also included tracing car licenses to the homes of men Humphreys did not interview in the field in order to interview them subsequently without disclosing his true identity. He took this step to offset any social class bias, based on his observation that better educated men are more willing to talk about their lives and these sexual experiences in the field. Although the study contributed to understanding a highly stigmatized behavior and to reducing stereotypes about homosexuality, it simultaneously created considerable controversy about covert observation, deception, and potential harm, from emotional and interpersonal to legal.[38–40] Like the Milgram and Zimbardo studies, this field research generated debate in the behavioral and social science community about the research procedures that Humphreys used. Although Humphreys sought to explicate the benefits of the research and reported that none of the participants subsequently expressed concerns about the deception or reported any harms, criticism about informed consent and deception eclipsed other issues.

Behavioral and Social Science Societies

During the 1960s, professional associations in the behavioral and social sciences also turned to a consideration of the ethical dimensions of research. The promulgation of ethics codes is perhaps the most tangible indicator of a commitment to articulate normative standards to guide and inform researchers in these fields. In taking up this task, scientific societies realized that periodic review of ethics codes would be necessary as knowledge evolved, methods developed, and contexts and issues emerged for study.

The American Psychological Association (APA) was the first professional association to take up this work and to use empirical methods to develop a code. The APA's critical incident method requested firsthand reports from some 7,500 members of decisions having ethical implications.[41,42] Instead of relying on a committee to identify issues, APA asked members to describe situations with ethical implications that they knew firsthand and to specify the ethical issues requiring decisions. Published in 1953, this code focused largely on psychologist-client relationships, in which the preponderance of incidents were reported.[43] In 1966, the APA established a Committee on Ethical Standards in Research that, also using the critical incident method, produced *Ethical Principles in the Conduct of Research With Human Participants*, which was adopted by APA Council.[44] The *Principles* became a new component of the APA Ethics Code published in 1972[45] and in all subsequent code revisions during that period.[46] The *Principles* was revised and reissued in 1982.[47] In 1992, the APA adopted a further revision of the code,[48] which was buttressed by publications related to human research participants.[49,50] The most recent revision of the Ethics Code appeared in 2002.[1]

By the late 1960s, other behavioral and social science societies took up this task as well. In 1967, the American Sociological Association (ASA) reactivated a process that had commenced in 1960, and by 1969, a Code of Ethics was approved by 88% of eligible members voting.[51] The ASA also saw its code as a dynamic document, with revisions being approved in 1982 and 1989, and enforcement procedures put in place by the ASA Council in 1983.[52] A major revision was approved in 1997.[2] The American Anthropological Association (AAA) initially addressed ethical issues in its 1967 Statement on Problems of Anthropological Research and Ethics.[53] By 1971, the AAA had adopted an ethics code, *Principles of Professional Responsibility*,[54] which was followed by amendments and a revision in 1990[55,56] and a further revision in 1998.[3]

The American Political Science Association (APSA) also addressed ethics in human research in the late 1960s. The APSA Committee on Professional Standards and Responsibilities issued a report in 1968 entitled "Ethical Problems of Academic Political Scientists," with a Standing Committee on Professional Ethics being established as a consequence.[57] Not until 1989, after a period of evolution, were these standards formalized;[4,58] they were further revised in 1998.[4] With funding from the Russell Sage Foun-

dation in 1975–76, the APSA led 12 other social science associations[59] in undertaking a survey about confidentiality in social science research that yielded a statement, entitled "The Scholar's Ethical Obligation to Protect Confidential Sources and Data," and recommendations were approved by the APSA Council in 1976.[60]

Overall there was progress commencing in the late 1960s and 1970s in social and behavioral science societies' initiating activities and formalizing codes.[11] Nonetheless, some of the same ambivalence and tensions articulated by individual researchers about the balance between strengthening human research ethics and overregulation were also evident. Thus, the deliberations taking place in professional associations revealed an impulse to lead, but also to crystallize an evolving consensus in the formulation of ethical standards. Over time, for example, codes of ethics became much more explicit about informed consent[61] and about the use of students in research.[41] The evolution of federal regulations in this area similarly reflected an evolving consensus about ethical practices and how they should guide operational research.

Inclusion of Behavioral and Social Sciences Research in Federal Policy Making

Even in the earliest language and consideration of federal policy related to human research protection, discussions made reference to behavioral and social science research. Gray[62,63] traced the first inclusion of social and behavioral research back to a July 1966 revision of the February 1966 U.S. Public Health Service (PHS) policy that required institutional review of human research in all PHS awards.[64] Quoting from Gray,[62] the July 1966 revision stated that

> there is a large range of social and behavioral research in which no personal risk to the subject is involved. In these circumstances, regardless of whether the investigation is classified as behavioral, social, medical, or other, the issues of concern are the fully voluntary nature of the participation of the subject, the maintenance of confidentiality of information obtained from the subject, and the protection of the subject from misuse of the findings. . . . [social and behavioral sciences sometimes use procedures that] may in many instances not require the fully informed consent of the subject or even his knowledgeable participation.

Any ambiguity as to the intent of this language was further clarified in December 1966, when the U.S. Surgeon General, in response to a question, stated that the policy "refers to all investigations that involve human subjects, including investigations in the behavioral and social sciences." Furthermore, PHS policies issued in 1968 ("Public Health Service Policy for the Protection of the Individual as a Subject of Investigation") and 1969 ("Protection of the Individual as a Research Subject: Grants, Awards, Contracts") explicitly included behavioral and social science research, focusing in particular on risks that might be incurred due to breaches of confidentiality and misuse of findings. By 1971, in response to requests for better understanding of policy and the need for more uniformity in institutional review, the Department of Health, Education, and Welfare (DHEW), which preceded the DHHS, issued "The Institutional Guide to DHEW Policy on Protection of Human Subjects." This Guide dealt with concerns about physical, psychological, sociological or other harms and explicitly addressed harms, beyond physical harms, that could arise in behavioral and social science research.

The National Research Act of 1974 established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (National Commission) and required the establishment of a board to review biomedical and behavioral research involving human subjects at institutions that apply for funding from the PHS. The Act also affirmed the new DHEW regulations for the protection of human subjects (codified at 45 CFR 46) that required research to be reviewed and approved by committees as a prerequisite to funding. The behavioral and social science community expressed concerns about the potential suppression of research on controversial issues under the guise of ethical considerations; about the emphasis on a written document as part of informed consent, especially given ambiguous statements about waivers and documentation of consent; and about whether the regulations would be meaningfully extrapolated from biomedical and clinical settings to some of the challenging contexts and issues that animate social and behavioral science research (e.g., studying socially harmful behaviors or unsavory topics or persons). Concerns were also expressed about the very limited involvement of behavioral and social scientists on the National Commission or staff, although a number of papers were ultimately requested from these scientists by the National Commission.[62]

Over the four years that the National Commission worked (1974–78), behavioral and social scientists' level of engagement in research ethics increased. By 1979, when proposed revised regulations were published for comment in the *Federal Register*, the behavioral and social science community was better situated to respond. Comments ranged from encouraging ethical guidance that was better aligned with the designs and methods of the behavioral and social sciences to completely resisting any regulatory policy for social and behavioral science research. The federal regulations adopted in 1981 reflected the strengths of the National Commission's work and the urgings of the behavioral and social science community to specify a more nuanced understanding of risk, types of harm, and categories of review. Areas of research that could be exempt, areas that could be handled through expedited review, the capacity to waive documentation of consent, the definition of human subjects research to include *living* persons and identifiable *private* (not public) information were improved features of the 1981 revision. The National Commission's articulation of the core principles that formed the basis of the Belmont Report (i.e., respect for persons, beneficence, justice) as well as its openness to comments were important to the fuller integration of behavioral and social science research in federal policy.

Literature at that time[62,63,65] and later[14,66,67] provides an overview of the evolution of the 1981 federal regulations and the role of the National Commission in the development of these regulations. During the 1980s and the period that led to the adoption of the Common Rule (subpart A of the regulation) by federal agencies in 1991, behavioral and social science research operated within federal policy without much profile. By the late 1990s, with heightened public and policy attention to human research protection and the role and functioning of institutional review boards (IRBs), some of the same concerns expressed in the 1970s about one-size-fits-all solutions, the dominance of the biomedical model, and hyperregulation resurfaced in the behavioral and social sciences.[68,69]

Emerging Empirical Research on the Ethics of Research

Since the late 1990s, in addition to formal institutional responses in the form of new federal advisory committees, new National Academy of Sciences' committees, and initiatives of scientific societies, there have also been calls for better empirical knowledge about ethical aspects of human research in light of the methods and practices in these fields.[14,68,70] Assumptions abound about such issues as what research participants consider to be personal or private information, what they consider to be of risk or benefit, and what they believe they need to know before agreeing to participate in certain forms of research. To date, the literature on human research ethics largely remains more analytic or assumptive than empirical.

Work in the arena of survey research, addressed primarily to consent and confidentiality, is a major exception. Singer's work in particular stands out in this regard. Since the late 1970s, Singer has undertaken extensive research on such issues as the effect of the amount of information on consent and the impact of the request for and timing of written consent and confidentiality assurances (with sensitive and nonsensitive information) on response rates and response quality.[71–74] Singer reported that 8% of her sample refused to sign consent forms, but were willing to be interviewed—a finding consistent with a study by Ellikson and Hawes.[75] She also reported that when sensitive information is involved, confidentiality assurances matter in terms of willingness to respond and response quality, but confidentiality assurances have no significant effect when the content is not sensitive, complementing the findings of Turner[76] and of Boruch and Cecil.[77]

Much of the research in the 1970s was stimulated by the Privacy Act of 1974 and the 1974 federal regulations for the protection of research participants. In reflecting on this research in two review studies published in the 1990s,[78,79] Singer called for far more empirical inquiry on ethical issues in research. Over a wide range of issues and areas, the number of studies continues to be small in relation to the ethical questions about human research that could be informed by a critical mass of work. Singer's 2004 research, for example, has turned to the important issue of examining willingness to participate in surveys given perceptions of risk of disclosure, perceived harm, and perceived benefit.[80] Focusing on children and youth, Fisher has undertaken research on such issues as adolescents' assessment of investigators' use of varying options (such as maintaining confidentiality, reporting to parent/adult, encouraging self referral) under hypothetical conditions of investigators observing adolescents at various levels of jeopardy.[81] She has also been studying the capacity of children and youth to understand their rights, with younger children comprehending information but having less comprehension of their rights as research participants.[82] Others, like Hull and colleagues, are studying strategies for recruitment of family members in research in addition to the indexed participant.[83]

There has also been a resurgence of interest in studying IRBs, a topic that—despite its inherent interest and value—has received scant research attention[84] since the University of Michigan surveys undertaken by Gray and associates[63,85,86] as part of the work of the National Commission. Since the late 1990s, there have been additional commissions[87] and government reports[88] about IRBs that utilize or make reference to studies or data, but, over almost a 30-year period, only a modest number of studies has surfaced across a spectrum of issues. For example, in 1985, Ceci, Peters, and Plotkin reported on an experimental study of IRBs' responses to hypothetical proposals that differed in sociopolitical sensitivity and ethical concerns (e.g., presence or absence of deception, debriefing).[89] They found that when the purpose of the research was presented to IRBs as nonsensitive, the protocol was twice as likely to be approved. In 1995, Hayes et al. reported on a survey of IRB members at research universities, finding that over half received minimal or no training.[90] In 2003, Wagner, Bhandari, Chadwick, and Nelson reported on the costs of operating IRBs and economies of larger IRBs.[91] And in 2006, two studies were published that focused on investigator experiences, understandings, and perceptions of IRBs.[92,93]

Renewed attention and calls for empirical research on research ethics have been matched by some federal funding initiatives. In particular, the DHHS Office of Research Integrity commenced an extramural program of support in 2001. Also, the inauguration in 2006 of the *Journal of Empirical Research on Human Research Ethics* (JERHRE), dedicated to publishing empirical research and reviews of empirical literature on human research ethics, can be expected to further catalyze attention to inquiry on these issues.[94]

Ethical Issues in Research Contexts

The dearth of scientific knowledge about human research ethics adds to the challenge of undertaking research in all of the human sciences, including in the behavioral and social sciences. Nevertheless, absent deeper empirical knowledge, ethical considerations need to be weighed sensitive to the contexts of study and the fundamental principles of beneficence, respect, and justice specified in the Belmont Report and in codes of ethics. Key to making ethical decisions is to assess choices as part of the process of specifying the research design and methodology.

Complexity of Ethical Considerations

Behavioral and social science research draws on a range of research designs and methods in examining the complexities of human behavior—individually, in groups, in organizations and institutions, and in communities. Although different social science methods may be more frequently used or relied on by different behavioral and social science disciplines, almost every method is used to some degree in each behavioral and social science field. In addition, scientists increasingly draw on multiple methods in designing their research, even if there is primary reliance on a particular method.[95] The range of methods and multiple methods used in behavioral and social science research, the diverse populations under study, and the spectrum of issues (from mundane and everyday to highly sensitive and personal) make ethical considerations challenging and not amenable to easy characterization, generalization, or solution.

An emphasis on design and methods helps to identify ethical considerations across the behavioral and social sciences and between these sciences and the biomedical sciences—whether weighing autonomy, privacy, trust, benefit, or harm. Levine effectively dissected such issues in his 1976 paper "Similarities and

Differences Between Biomedical and Behavioral Research,"[96] prepared for the National Commission, and in his now classic volume *Ethics and Regulation of Clinical Research*.[97] Macklin also made an early and helpful contribution in her examination of disclosure in social science research.[98] Most comparisons between behavioral and social science research and biomedical research implicitly contrast the former to biomedical experimentation. It is from that vantage that behavioral and social science research is typically characterized as more likely to involve minimal risk for human participants because interventions in biomedical research have far greater potential for physical injury, harm, or adverse reaction.[14,99,100]

Leaving aside the additional complexity of research on special populations (e.g., children, prisoners), much of behavioral and social science research involves little interaction or intervention that could elevate risk beyond the minimal level, taking as the standard 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."[6] Nevertheless, assessment of risks and benefits still comes into play in planning and implementing behavioral and social science research. Although the potential for physical harm or discomfort are rare, the risks are considered when appropriate—as is the potential for psychological, social, economic, or legal harm.[101,102] In some instances, the research activity itself could produce psychological discomfort or harm from feelings of being inconvenienced, embarrassed, or tired or from transitory stress or anxiety to more traumatic emotions or experiences. In most instances, risk of social, economic, or legal harms follows from insufficient protection of private information during the actual research or from breaches of confidentiality (including a person's anonymity) thereafter.

As suggested by the above, the substantive topics of inquiry may themselves cause psychological stress—from minor and transitory to more serious. For example, a research study on obesity that asks participants about their eating habits may cause minor and transitory stress. Research examining social support after the death of a loved one could cause a greater level of stress for participants because it evokes deep memories of sadness. Similarly, a retrospective study of adults who suffered child abuse could stimulate recollections that produce stress that is more than transitory or exceeds what persons would experience in everyday life. Research topics may also create the possibility of reputational, economic, legal, or physical harm that would exceed standards of low or minimal risk were there to be a breach of confidentiality. For example, a study of physicians charged with medical malpractice could produce reputational, economic, or legal harm were the identity of the physicians or the information they provided to researchers become known outside of the research setting. In each instance, precautions need to be taken to ameliorate or reduce the level of risk.

The biggest risk in behavioral and social science research most often relates to disclosure of a person's identity and information about him or her. Even in nonsensitive matters, a promise of confidentiality is typically part of the process of obtaining consent from research participants. How such consent will be obtained, whether the information will be preserved and for what purposes, who may have access to such data, and the consequences to research participants of any breach, even with seemingly quite everyday issues (e.g., a study of exercise practices at a gym that might reveal to an employer that the research participant was not home sick that day) need to be weighed in order to honor the explicit or implied agreement between research participant and researcher.

The next sections of this chapter address the operational processes involved in weighing ethical issues in research involving human participants. The emphasis is on considering the potential for risk and strategies for risk reduction in the context of planning and implementing research because, even in areas of minimal risk, it is incumbent upon researchers to design their research in ways that maximize benefits and reduce risk as well as protect against circumstances that could inadvertently raise risk levels. At least in principle, the responsibilities of investigators in this regard are generally quite well understood.

The attention to risk in these sections is not to eclipse consideration of the very real benefits that can flow from behavioral and social science research and that need to be weighed in a risk/benefit assessment. Indeed, behavioral and social science research can provide a wide range of benefits, including insights into human behavior or the practices of a particular culture, determinations regarding best therapeutic methods or educational practices, or strategies for addressing developmental challenges for children and the elderly. The results of this research may have a direct benefit for participants (e.g., decisions regarding work hours in an organizational setting) or may benefit society more generally by influencing broader public policy decisions (e.g., limited hours for workers in high-risk occupations). The benefits that derive from research are an important part of the equation in reviewing research and assessing risk and risk tolerance under varying circumstances.

A Heuristic Model for Guiding Ethical Considerations

A number of scholars have recognized the complexity of weighing ethical considerations and have sought to map the relationship between types of research and ethical issues. Kelman, for example, schematized the relationship between types of research, the concrete interests of participants, and potential effects of the research on participants and on larger social values.[26] Cassell also depicted the relationship between investigator, research participants, and research in the context of studies ranging from biomedical and psychological experimentation to fieldwork, nonreactive observation, and secondary analyses of data.[103] She characterized the contexts in which investigators have more (or less) power as perceived by participants or have more (or less) control over the context or setting of research. Using a more complex framework, Sieber, too, graphed how the assessment of risk (from mere inconvenience and social risk to legal, psychological, or physical risk) can best be assessed in the context of a scenario that takes into consideration aspects of the research activity (e.g., the research processes, use of research findings), the risk-related factors (e.g., privacy and confidentiality, deception and debriefing), and the vulnerability of the persons and institutions involved (e.g., those visible or public, those engaged in illegal activities).[104]

This chapter benefits from the ideas presented in these frameworks, but presents a three-dimensional model to inform ethical decision making that is more centrally focused on the core elements of the research: the methods, characteristics of the study

population, and the type of inquiry. As noted in the introduction to this chapter, the ethical issues raised by the use of various methods are closely tied to the population under study and the type of inquiry. Figure 32.1 depicts the interaction between the degree of substantive sensitivity of the study, the level of methodological intervention, and the degree of vulnerability of the human participants. This three-dimensional model views the potential degree of risk to follow from a combination of the method used, person characteristics, and the nature of the research.

In Figure 32.1, the *y* axis characterizes the level of methodological intervention in relation to research participants. It varies from no interaction (e.g., the use of extant public data or records), to indirect or direct contact (e.g., survey or interview) to intervention (experiments). This continuum generally reflects the centrality of the intervention or interaction to the definition of human subjects research, as specified in 45 CFR 46.102(f).[6] Methods vary in the level of intervention with human participants (or their environments), and the level of research intervention can introduce risk. However, risk associated with methods is not a function only of the degree of intervention. Methods also vary in the amount of control an investigator has over the potential for risk (e.g., laboratory settings provide for a higher degree of investigator control than field studies) and in the degree of actual invasiveness (e.g., video recordings in public places can be more invasive than a laboratory intervention on a relatively mundane issue). In selecting methods, investigators should weigh the scientific appropriateness of certain approaches cognizant of the value of minimizing or ameliorating the level of risk.

The *x* axis is the research population gradient and represents the level of human participant vulnerability. Any number of factors (biological, social, psychological, cultural) may influence where a research participant falls on the continuum. Federal law recognizes the vulnerability of certain populations of study (pregnant women, fetuses, and neonates; prisoners; and children), creating additional regulations for research involving these groups. The representation of participant vulnerability on a continuum allows viewing these and other potentially vulnerable groups (e.g., students, those in low-income brackets) on the same scale. It also permits depicting participants' vulnerability to heightened risks as a function of the characteristics of the population under study as distinct from any normative judgment about the desirability of protecting that population (e.g., studies of doctors engaged in insurance fraud or pharmacists engaged in illegal drug sales) or whether that population should otherwise receive any direct benefit at all. The responsibility of the investigator is to ensure that the vulnerability of human participants is not increased by virtue of being a part of the

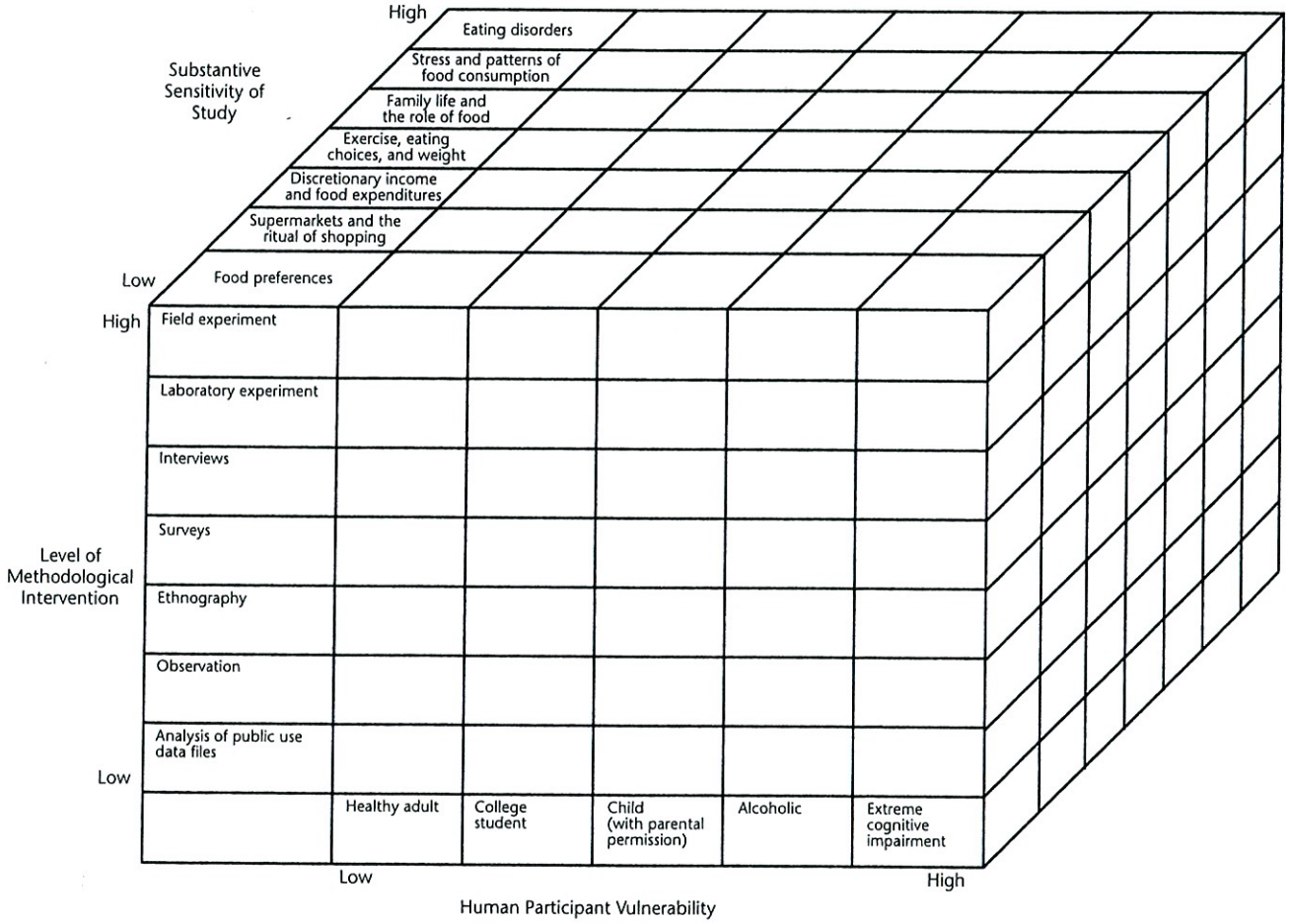

Figure 32.1. Risk in Research as a Function of Substantive Sensitivity of Study, Level of Methodological Intervention, and Human Participant Vulnerability.

research and being willing to contribute to the advancement of important knowledge.

The third dimension (z axis) displays the sensitivity of the study topic using, for heuristic purposes, illustrative studies about human interaction regarding food and consumption behavior. The sensitivity or the invasiveness of the research topic affects the level of risk in behavioral and social science research—from discomfort or embarrassment through anxiety, legal liability, and so forth. Figure 32.1 shows that risk level in matters of substance also interacts with the populations under study and the methods being employed. Although the invasiveness of the inquiry is often viewed alone in an analysis of risk, in reality it operates in concert with other factors that together shape risk.

The three dimensions highlighted above—level of methodological intervention, human participant vulnerability, and sensitivity of the study topic—interact to determine the level of risk. The next sections focus on factors that influence the risk of harm and consider the implications for the informed consent process and issues of confidentiality from the vantage point of different methodological approaches: experimental, observational, survey, interview, ethnographic, and analysis of public data files. The reader should note that although methodologies may overlap in any single study (e.g., the use of observation in experimental research), for purposes of clarity, each method is discussed separately.

Ethical Challenges

Experimental Methods

The experimental method provides a direct way of testing the cause and effect relationship between variables. Behavioral and social science experiments can occur in laboratories or in external field settings, including the school, community center, hospital, workplace, or neighborhood, to name but a few. This method, widely used by both biomedical and social scientists, is defined by the manipulation of a variable of interest, random assignment of participants, comparison of treatment or intervention and control conditions, and control of extraneous factors.

Take, for example, an experiment designed to test cognitive functioning under stress in older adults. The investigator gives experimental participants a task that is designed to tax their working memory and compares the results to those of a control group. First, the introduction of a manipulation of the environment alone raises ethical issues because such an intervention would not otherwise be experienced by the research participants. Because the researcher is changing the situation to which people would ordinarily be exposed, he or she has an obligation both to minimize any risks involved and to make those risks known to potential participants during the informed consent process.

The researcher who introduces and manipulates a variable must take care to examine the nature of the variable—its intensity and duration. In experimental research, investigators search for the level of intensity and duration that will produce an effect akin to what would occur in the lives of participants (referred to as experimental or mundane realism). An intervention may be positive, neutral, or negative and should not be assumed to be adverse. For example, the effect of relaxation exercises on workplace productivity for those in high stress jobs could be a very pleasant and satisfying intervention. The effect of group size and composition on problem solving may be a neutral manipulation. With interventions that may stimulate adverse states—such as tedium, anger, or performance anxiety—examination of the nature of the variable (both its intensity and duration) provides insights into the amount of invasiveness and its contribution to overall risk. If risk of an adverse state is beyond what might be expected in everyday life, the researcher may reduce the intensity of a planned intervention with the more limited goal of identifying triggers and mechanisms without risking substantial adverse behavior.

In planning and implementing experiments, the investigator needs to consider possible psychological and emotional consequences when germane. How is the manipulation of the situation viewed by the participant? Is the impact of the intervention (whatever its intensity or duration) transient? What will research participants be told about the research in advance of the study? Will debriefing return participants to their preexperimental state? In other words, does the manipulation increase risk for the research participant, and, if so, does the debriefing reduce it?

The design of the experiment can also have an impact on ethical considerations. A long-term sustained intervention may, in some instances, increase risk for research participants. For example, in an experiment designed to test the impact of images of aggression (e.g., shouting, pushing, hitting) on teenage behavior, those images that more closely approximate what teenagers experience in their daily life may pose less risk than those that exceed what they typically experience. Furthermore, the intensity and duration of the exposure may have an impact irrespective of the typicality of the depictions. Repeated exposure to a series of aggressive images may increase the level of fearfulness or of engaging in aggressive behavior. How participants may be affected by repeated exposures will be determined not only by characteristics of the methods, but also by individual factors. In this example, the risk to teenagers who have been abused or live in violent neighborhoods may be different in unknown directions than the risk to teenagers who have not had these experiences (e.g., at-risk teenagers may be desensitized or alternatively reaffirmed by the images).

Field experiments include randomized control trials and quasi-experimental designs that aim to test how modification of conditions can change behaviors or beliefs of individuals or groups. Experiments in the field alter the external environment (e.g., types of drug counseling, alternative strategies for teaching reading) that can affect the lives of those exposed to a treatment or control. The same ethical guidelines that apply to clinical medical trials apply here (e.g., one treatment should not offer more of a known benefit than another). Although experiments in the laboratory allow researchers to achieve a high degree of internal validity through careful controls, field experiments are introduced into real-world settings and thus have the potential for far greater external validity. Field experiments with randomized control designs are much more complex to plan and implement (from access to sites and agreements about the form of a manipulation to continuing follow-up to ensure consistent implementation of the treatment). Quasi-experimental designs are often introduced in the field when the context may require some alteration of a strict experimental design to be feasible. The classic texts by Campbell and Stanley[105] and by Cook and Campbell[106] provide more detailed descriptions of experimental and quasi-experimental design.

A field experiment might compare, for example, a novel intervention aimed at reducing risky sexual behaviors among teens with a control group that receives a standard educational

intervention. The introduction of a variable into a natural as opposed to laboratory setting raises some unique ethical challenges: How is the variable introduced into the setting (e.g., individual education sessions or community wide)? Is the intervention visible to others, thus posing additional risks for human participants (e.g., being seen by neighbors or friends entering a clinic for treatment)? Does the intervention have a broader or spillover effect? If so, is the effect transient? Is the effect of the intervention desirable or undesirable? If the experiment is occurring in a natural setting, is there sufficient attention to privacy protection? If people are unaware that the research is occurring, is there sufficient respect for the autonomy of research participants to determine whether they wish to be part of the research? If research participants are members of a vulnerable group (e.g., prisoners, teens, at-risk teens), how, if at all, does this increase risk?

Naturalistic experiments also arise in the conduct of social and behavioral science research. A change in legal regulations about drug use, for example, may provide an apt opportunity for a before-after design or a case-control comparison to sites that have not had such change. Interventions may be person-made (as in the case of a change in regulations, policy, or practice) or may be naturally occurring. A naturally occurring event like a hurricane or other disaster affords an opportunity to study certain aspects of human behavior with a before-after design or through comparison (e.g., a study of the reactions of people at varying distances from the site of a disaster). In such an instance, risk in the form of emotional trauma may vary in terms of research participants' locations. It may be more intrusive to ask people to participate in a study than to observe their interactions with neighbors, police, or clergy. The researcher needs to examine carefully the methods, nature of the inquiry, and participant vulnerability in order to make an assessment regarding ethics in these different situations.[107] Obtaining the input of an independent group of scientists and community members as part of the IRB review process can serve as an important check on the process.[108]

Observational Methods

As with experiments, observational methods can be used in a range of research contexts from the carefully controlled setting of the laboratory to the field. In evaluating level of intrusion or possible risk, most researchers tend to focus on whether the behavior occurs in a public setting. However, the expectations of people in a particular setting also need to be considered. In using observational methods, researchers must consider (1) whether the setting is public or private and (2) whether the behavior is public or private. Although these variables can be placed on a continuum, in Table 32.1 we depict them in a 2 × 2 matrix for illustrative purposes.

Table 32.1
Illustration of Interaction of Public and Private Dimensions in the Observational Method

		Setting	
		Public	*Private*
Behavior	*Public*	Observe alcohol use at baseball game	Observe alcohol use at open-house holiday party
	Private	Observe discussions of alcohol use in Internet chat room	Observe alcohol use in in-home family study

Table 32.1 shows the interaction of public-private setting and public-private behavior through an example for each cell. Observations of spectators' consumption of alcohol at a baseball game would be considered public behavior in a public setting. Spectators enter this setting assuming that behavior will be observed by others and possibly even recorded (e.g., in photos or videos by other spectators). Observations of public behavior in a public setting are not considered invasive, and risk is generally considered minimal. However, how the behavior is recorded (e.g., field notes or video recording that serves as a permanent record) could potentially increase the invasiveness of the inquiry and the overall risk, and could make data that are otherwise unidentifiable potentially identifiable, thus transforming the observations into human subjects research as defined in the federal regulations at 45 CFR 46.102(f)(2).[6]

Even behavior in a public setting can easily be considered private when people's expectations change. The public setting–private behavior cell is probably the area that causes most concern for investigators. Behavior in a public setting can be considered public by a researcher, but the expectations of the participants in this setting need to be considered in making decisions about responsibilities to human participants in this research. For example, Internet chat rooms may be considered public settings in that any member of the public can access them and become involved in a conversation. However, a number of these chat room discussions involve highly personal and sensitive matters. Although one might argue that participants should consider their behavior public, their expectations may be otherwise. Humphrey's tearoom trade study,[37] mentioned earlier, provides another example of the public setting–private behavior overlap. Although the setting was a public restroom, most men probably considered their behavior private.

In an Internet chat room, the use of observational methods may involve no interaction or intervention (i.e., when the researcher's identity is concealed and participation is minimal to nonexistent), but the nature of the inquiry may still be considered invasive from the viewpoint of chat room users' expectations of what might reasonably be expected to occur in this situation. Those who are less aware that the setting is public (e.g., an elderly person with less knowledge of the Internet) are more vulnerable than those who realize its public nature. In addition, risk is increased if the sensitivity of the information can potentially harm research participants. If an investigator is monitoring and recording discussions of alcoholism in an Internet chat room, the information could have economic, social, and legal risks for the participant. Researchers can decrease the vulnerability of participants by recording observations in such a way that identities cannot be traced. In addition, although this setting can allow researchers to remain anonymous and this feature of the design can be important in understanding human behavior in real-life situations, the fact that a researcher's presence is unknown increases the level of invasiveness and risk for those involved because their ability to monitor and control self-presentation to fit the context is reduced.

In the private setting–private behavior cell, both setting and expectations combine to increase the potential risk to participants. First, the home itself is generally considered to be a private place. Second, most private behavior occurs in the home. Participants in

an in-home family study may consider the recording of observations about alcohol use to be intrusive despite their agreement to be involved. Special precautions should be taken to ensure fully informed consent and to plan confidentiality protections in advance. Here, privacy concerns are elevated, but proper informed consent can reduce ethical concerns about overstepping participants' expectations. In addition, taking steps to protect the confidentiality of the data can reduce the risk to participants.

Finally, observations of public behavior in a private setting should also be guided by participants' expectations. Although a home is typically considered private, behavior in the home may be considered "public" if, for example, a homeowner invites residents in the neighborhood into the home. One might reasonably expect that observations of alcohol use by other partygoers at an open-house holiday party could be discussed outside this setting. Still, a researcher's observation and recording of alcohol use at a party may be considered more intrusive than observations by party guests, and how such data are gathered can have different implications for the perceived intrusiveness of the inquiry. Making known a researcher's presence will decrease the perceptions of invasiveness and is more respectful of the autonomy of potential research participants who can decide whether to leave or stay. Acknowledged observation or participant observation in this context gives individuals more control over the situation than if the researcher fully conceals her or his identity. What form the research design should take and what the consent process should be (i.e., how much information should be revealed by the researcher in order to act ethically in obtaining valid data) need careful assessment by the researcher and independent assessment by an IRB, especially if the researcher seeks to waive some or all of the elements of informed consent.

Survey Methods

Survey research methods are widely known in the general public and are used in a range of studies from specific institutional or organizational contexts and small area population studies to major national or international surveys on general adult populations or on specialized populations of adults, children, or youths. Of behavioral and social science methods, survey research may be best known to the public because it is the social science method that has had the widest application outside of the social and behavioral sciences by, for example, commercial, political, and media organizations. The federal government also oversees many large-scale survey research projects. For example, in order to monitor the health and well-being of the population, the government regularly undertakes the National Health Interview Survey.

The level of risk in any survey is affected by several factors that may interact and affect overall risk. Specifically, the factors influencing the risk dimension include questionnaire content (sensitivity), mode of administration, recruitment strategies, mechanisms to increase participation, and the actual survey design (e.g., cross-sectional or longitudinal). Other factors influencing total risk are the population studied, anonymity of the responses, person or entity collecting the data, and data usage and storage. Together, these factors determine the level of risk in a survey. Each is described below.

The factor receiving most attention in survey research is the questionnaire content. Survey methods are used in a variety of substantive areas covering topics ranging from those with little or no sensitivity to those that may be considered highly sensitive. For example, questions about personal health information are generally considered more private or invasive than those that ask about product preference. Similarly, the mode of administration (e.g., telephone, mail, Internet, in person) affects whether participants think the procedure is more or less invasive. Mail surveys, especially anonymous ones addressed to "resident," are less intrusive than a face-to-face interview in the home. Telephone surveys and Internet surveys fall between these two points. Participants may perceive a certain degree of anonymity when responding to Internet surveys, thereby decreasing the perceived level of invasiveness (even if responses could ultimately be traced). From the human participants' perspective, the type of questions asked and how they are administered affect their view of the level of intrusion and the perceived risk associated with the survey.

Although surveys cover full populations under study, typically they are aimed at a sample of a population selected from a specified frame, however it is identified (often that means use of a list of potential participants who have attributes in common). If researchers access a publicly available list (e.g., a phone book) or obtain or construct a list from public information (e.g., a map of housing units in census track areas), participants are less likely to consider this an invasion of privacy because they know that the records are publicly available than if the researcher obtains a private list (e.g., a club membership list) that is not generally available. How potential respondents are identified (that is, the sampling frame from which they are drawn) and how they are approached are important in determining participants' perceptions of invasiveness and potential risk. Being asked to participate in a local or national household survey is less invasive and potentially less anxiety-arousing than being approached to participate in a survey as a cancer survivor or because a person is living in a community in which the water has a high lead content.

The quality of survey research is inextricably tied to the representativeness of the sample. Survey researchers employ a number of techniques in order to improve response rate such as callbacks, persuasive introductory or interviewing scripts, or incentives in the form of payments for research participants' time. Properly employed, these techniques can strengthen response rates without being overly intrusive, coercive, or infringing upon an individual's right to privacy. Interestingly, modern technologies such as unlisted cell phone numbers raise problems in sampling designs that can reduce the quality of the survey and thus, the benefits of conducting the research.

The design of the survey can also affect the potential level of risk. In longitudinal versus cross-section designs, there are many more scientific payoffs and potential benefits in terms of causal modeling and identifying patterns of behavior, but longitudinal research can require more from research participants in the amount of cooperation, and repeated follow-up can raise potential risk. Longitudinal designs that seek participation for long spans of time increase the opportunities for participants to be identified in contrast to cross-sectional designs (i.e., one-time-only collections of data), but sensitivity to how subsequent contacts are made and how data linkages are protected can avert increasing disclosure risk.

The level of potential risk is also affected by whether identifying information is obtained or retained. For example, if random-digit dialing is used in a telephone survey, individuals can remain anonymous. In household surveys, individuals are not

anonymous; however, one's responses can be protected by data security and data access plans consonant with the level of sensitivity of the substance of the study. Despite these efforts to protect participants' identity and personal information, other inadvertent disclosures could occur. For example, during a phone or in-home survey, family members may overhear all or part of the conversation and convey that to others. Similarly, research assistants may inadvertently risk identification of participants by sharing examples of interesting cases with others outside the research team. In both instances, the risk level for participants is increased, but the rarity of such events and the nature of the harm or discomfort itself may not generally exceed the everyday standard of minimal risk.

Under federal regulations, surveys of healthy adult populations are exempt from review by IRBs if participation is anonymous and the topic of inquiry presents no more than minimal risk for respondents. Surveys that include identifier information may qualify for expedited review by IRBs if they are on healthy adult populations and if the topic of inquiry and the possibility of information disclosure involve no more than minimal risk. On the other hand, federal rules recognize the inherent vulnerability of children and, as such, require IRB review of surveys involving children. Even with adult populations, however, vulnerability and level of risk may vary. For example, paying low-income persons to participate in a study suggests a different level of potential coercion due to personal characteristics than providing the same payment to a middle-income person, and differential payments can raise questions about just and equitable treatment of human participants. Thus, the vulnerability of the population requires consideration in implementing the survey design and research.

Interview Methods

The level of risk in interviews is affected by many of the same factors as in surveys, such as the content of the questions, the population studied, and how the data are used and stored. There are, however, ethical factors that are more particularistic to the interview method. Surveys that are administered in person raise some of the same concerns. Four issues, in particular, need to be considered: degree of structure in the interview; unanticipated but sensitive responses; disclosure following group interviews; and recruitment through the use of interviews.

In behavioral and social science research, interviews can range from highly structured to unstructured formats. In some research, a list of questions is systematically designed, although not to the level of a survey instrument; in other studies, the interviews may be guided by only a general map. Alternatively, the researcher may prepare a general framework with specific questions that will vary depending on what issues are raised by the respondent in answering earlier questions. Follow-up questions may or may not be specified at the onset, depending upon the research training and tradition in which the investigator is grounded.

As one example, a researcher using a semistructured interview may create an "interview guide" that, for example, lists a range of questions by topic area: introduction (questions about the nature of the study and consent to participate), background (family, friends), and drug use (friends' drug use, personal drug use, multiple drug use), sexual experiences following drug use (who initiated, safe-sex practices). Here, subsequent stages of the interview would be guided by answers earlier in the interview. Questions about multiple drug use would be skipped if respondents indicate that they use only one drug. Similarly, questions about sexual experiences after drug use would be skipped altogether if respondents indicate that they do not use drugs.

In a structured or even a semistructured interview, the questions can be reviewed to determine the level of invasiveness (e.g., the sensitivity of the questions) as well as participant vulnerability (e.g., the appropriateness of the questions given the study population). In an unstructured interview, consideration must be given to the fact that a more open-ended procedure implies less control about what the interviewer might ask or what might be revealed by the participant, even if the level of invasiveness and the participant vulnerability remain unchanged. Unstructured interviews can also provide an opportunity for the interviewer to build rapport and a trusting relationship with research participants, enhancing the experience of participants and the quality of their responses.

Investigators conducting structured or unstructured interviews may be aware of the questions or type of questions they will ask, but respondents may provide unanticipated answers in an interview session. In surveys, the number of open-ended questions is constrained, and responses are typically selected from among those provided. In interviews, on the other hand, response options may not be given, and the length and type of responses may vary considerably. Generally, the response does not raise ethical issues, but it could if the response (1) indicates activity that a researcher is legally required to report (e.g., child abuse) or (2) reveals other sensitive information that should be protected. Given that the respondent freely communicates the information, the response does not per se affect the invasiveness of the inquiry, nor does the intrinsic vulnerability of the participant change. Nevertheless, the method used (here, open-ended interviews) increases the risk for participants. Investigators can decrease risk by indicating in the informed consent process what information can be protected, how it will be protected, and, depending on the topic, whether the researchers are legally required to disclose to authorities any information revealed by the participants.

An additional consideration when evaluating risk in interviews is whether the information will be collected in a group setting. For example, a group interview of early career faculty about professional transitions, coping strategies, multiple time demands, and mixed messages about performance expectations could enhance the quality of the insights and understandings that come from peer interaction; but a group interview could also make these professionals vulnerable were their views or feelings inadvertently to become known. Highly sensitive questions that could be considered invasive typically are not asked by researchers when interviews are conducted in groups, but respondents may provide answers that increase their risk if they assume the session is confidential. Researchers can protect the information provided, but they cannot ensure that other participants will refrain from intentionally or inadvertently disclosing a respondent's answers. Again, the level of risk is affected by the group interview format.

Researchers can decrease risk by describing the extent of the confidentiality protections during the informed consent process and by training interviewers to "head off" responses that increase risk. Similarly, in a group setting, participants' judgments can be influenced by others, and doing so could increase pressure on them to respond, respond in a particular way, or remain in the interview session when they would not do so were they alone. Researchers should consider the impact of subtle group influence on risk and implement steps to decrease it.

Finally, interviews can be used to screen participants for other research studies or follow-up phases of the current study. How, where, and by whom participants are approached can contribute to the invasiveness of the research and the degree of risk. For example, it is less intrusive to approach people by phone than in a waiting room of a health-related facility. However, if research is conducted on low-income residents, a phone may not be available in the home and approaching potential participants at a clinic may be the best way to obtain a representative sample that does not exclude certain populations from the study.

Under this scenario, who should approach these clinic patients? If a health professional conducts the screening, it will probably be considered less intrusive, but these professionals may not have the time if the research protocol is not a part of their job. Also, depending on how the approach is framed, contact by health professionals either could offer more autonomy for potential research participants to consent or refuse to consent, or could lead to undue influence to consent. Alternatively, assuming approval by the clinic, can the researcher approach potential participants in the clinic waiting room? Although the intrusiveness of the inquiry might be slightly higher, overall risk might be decreased by better protecting the identities of research participants. Discussions with a skilled interviewer may actually be a positive experience for participants, especially for those persons who are lonely or need to be heard on an issue. Of course, the positive aspect of an interview experience may also lead participants to reveal more private information, placing more obligations upon the researcher to ensure that all information is appropriately protected and that participants do not increase the risk of any subsequent harm or discomfort by revealing more than they wish others to know.

Participant vulnerability should also be considered in deciding on the best approach: Are people participating because they are ill and think the information learned in the interview will help them, or are they healthy persons who came to the clinic for an annual checkup? It should not, however, be assumed that vulnerable persons are unwilling or unable to discuss or provide information about certain topics. Investigators or IRBs determining that certain issues are off-limits for certain groups can be disrespectful of individuals, limit their autonomy to be part of studies, and reduce the benefit of having certain forms of knowledge on the most vulnerable populations. Taking care to ensure that research procedures do not add to risk does not mean that research topics should be avoided.

Ethnographic Methods

Ethnography is the in-depth study of individuals and groups in their own environments. The method itself involves the use of multiple methods including unstructured interviews, semistructured interviews, unobtrusive observations, participant observation, and document or audiovisual analysis. Although this method is employed by researchers in many disciplines, anthropologists have typically used it most to provide accounts of particular cultures, societies, or communities. Ethnographers may focus on a particular topic in conducting their research (e.g., child-rearing practices), or they may be interested in more holistic study of the context or setting.

Ethnographic methods typically involve more than one research strategy and more than one type of research participant (e.g., drug users, community leaders, health-care workers). In a study of domestic violence in a rural African village, for example, an investigator may begin preliminary work by speaking to people in the community over a period of months to learn about the cultural norms and practices that may contribute to the problem. The investigator may follow the informal discussions with a semistructured interview of couples in the region. Simultaneously, the investigator may observe husband-wife interaction in public places to identify normative practices and the limits of acceptable behavior. Information obtained from ethnographic phases of a study may also suggest culturally sensitive interventions that could be tested in a field experiment.

The ethical issues associated with the use of this method can also be placed within the contours of our model. The invasiveness of the inquiry depends on the subject matter of the research and the vulnerability of the human participants who are the focus of the study. The method itself (or the bundling of methods) may also raise ethical challenges and dilemmas. For example, use of participant observation—especially if the research is conducted over long durations of time—can lead to attachments between the researcher and participants. A researcher studying domestic violence who has created emotional bonds within the community may have access to more and better information from participants. Also, the attachment may increase benefits for participants if they feel more at liberty to share information that previously they have found hard to discuss or disclose (e.g., information regarding abusive experiences, long-held family secrets).

A fundamental feature of the ethnographic method is to build trust between the researcher and the research participants in the study. If rapport is not effectively established, the investigator's presence may lead to perceptions of intrusiveness. Usually, however, the fact that the researcher lives in the community and often does so for a period of time before beginning research—typically in an attempt to identify the research directions, possible participants, and cultural norms—enables the researcher to build trust with community members and may decrease the view that an inquiry, however broad, is invasive.

The degree of risk may also be affected by the level of control inherent in the method itself. For example, the actual beginning and end of the research may not be clear because the researcher may have conversations with community members about their practices and beliefs before deciding where to focus the research. The researcher studying domestic violence may observe and speak to community members regarding views of male and female roles, use of alcohol, and the role of extended family or religion in influencing behavior. At times, conversations may be casual and unrelated to research, may lead to research, or may be a part of the research (in which case the consent of participants should be obtained). In addition, the researcher may come and go from a community over a period of time, at times interviewing people and collecting data and at other times casually observing community members for purposes of deciding the next step in research. Although the nature of the research may signal a need for flexibility with the approach, researchers can decrease risk by ensuring that community members are aware of the research and their roles.

Given the nature of ethnographic research, the pool of human participants is not always identified at the onset. A researcher may begin discussions with community and religious leaders in trying to understand the high incidence of domestic violence in a community, but later move to discussions with employers to determine

the role that job-related stress may play. As the researcher becomes immersed in a community and has a better understanding of it, he or she may choose to focus on certain members of the community. As the research progresses, other participants may also be identified. At these points, the researcher needs to engage potential participants in a conversation about the study and ascertain their interest in participating. If the discussions occur over a period of time, the researcher should continue to check the community members' willingness to participate. Thus, more than with other more targeted and time-bound methodologies, the consent process in ethnographic research is dynamic and ongoing—meeting the changing needs and circumstances of the research itself.

The risk associated with the method can be decreased by the use of a continuous consent process, as well as the flexibility to waive written consent when it would be culturally inappropriate, when participants are illiterate, or when use of consent forms could raise undue anxiety or place participants at risk. Indeed, in some cultures, being asked to sign a consent form may be considered an insult as a verbal agreement is valued. In some instances, it may also be appropriate to seek the consent of community leaders or elders, and community norms will suggest when this approach is congruent with human research protection or when it could elevate risk for research participants. Accounting for community norms, attending to the status of particular individuals in the community, and determining how consent should be obtained and whether it should be documented are elements of ethical decision making that can decrease overall risk.

Finally, as with other methods, the procedures used to collect, preserve, or store the information gathered can place participants at risk. Careful consideration of the protections available as well as individual and cultural expectations for the use and storage of the information can reduce the risk for research participants.

Analysis of Public Use Data Files

A great deal of information collected about individuals can be used in secondary analyses to examine important research questions, test rival hypotheses, verify findings, and so forth. For example, a wealth of information collected in periodic government surveys such as the Census, the National Education Longitudinal Survey, or the National Survey of Family Growth and in major national surveys such as the General Social Survey (GSS), the Panel Study of Income Dynamics (PSID), and the National Election Study (NES) can be accessed and used by other researchers. Some surveys like the GSS, the PSID, and the NES are undertaken to create data resources for multiuser analysis; other studies yield public use files that permit secondary study by other investigators (e.g., the National Longitudinal Study of Adolescent Health, the National Longitudinal Survey of Freshmen). The practice of creating public data files allows for greater use of a vast amount of data that would otherwise go unanalyzed and makes better use of limited resources to examine a range of behavioral and social science issues of scientific significance and societal importance.

By definition, public use data files refer to data that have already been collected and stripped of personal identifiers or altered to eliminate identifiable private information. Once these data files have been created and appropriately reviewed by an IRB or, in the case of a government agency, by a disclosure review board, they are no longer considered human subjects research as defined by 45 CFR 46(f),[6,109] although institutional IRBs individually act on their status.[110] Because public use data provide essentially anonymous information to the secondary analyst, concerns about invasiveness of this work or risk of harm are not at issue, though the research offers general benefits to those whose information contributed to these data sets.

The most challenging ethical issue associated with public data files is their creation; that is, de-identification of the data. Federal agencies, research organizations, and public archives (e.g., the Inter-University Consortium for Political and Social Research) take extreme precautions to de-identify the data before making them publicly available via the Internet or other media. Federal agencies and research archives that are responsible for holding data and making them accessible have the responsibility to ensure that data are de-identified if they are to be in public data files. The agencies and research archives are responsible for removing direct or indirect identifiers which could individually or jointly identify a person, such as detailed geographic information, birth dates, Social Security numbers, and exact income. A number of techniques are used by these data providers to remove both direct and indirect identifiers including eliminating variables entirely, aggregating categories instead of using exact values (e.g., using income brackets) or adding random noise to variables. De-identifying data files can be a complex process, and obtaining the advice or assistance of experts in this area is wise if the data preparation work is not being done by a professional archive or other data provider.

The process of de-identification to permit researchers' access is applicable to other forms of protecting confidential information beyond what is obtained in surveys and other systematic studies. In accordance with provisions in the Health Insurance Portability and Accountability Act of 1996 (HIPAA), researchers may be provided with individual health information without the individual's authorization if the data have been de-identified, an IRB or a privacy review board waives authorization, and the research is of minimal risk.[111,112] Two approaches are available under HIPAA: the first identifies 18 categories of data elements that must be stripped (limiting the usefulness of the data), and the second requires a separate determination by a statistical expert attesting to the fact that the risk of identification from the data being sought is very small.

Although the use of de-identified public data poses little risk, researchers may at times want to combine a public data file with a nonpublic data file. An enhanced file can increase the risk of identifying people, so further analysis of disclosure risk and de-identification are in order if these data are to become public use files. In circumstances in which individuals can be identified through the secondary use of extant data, or through linking of public use data sets that are otherwise de-identified, further data protection procedures are required to reduce disclosure risk. Archives like the Inter-University Consortium for Political and Social Research work with investigators on data preservation, data sharing, and the forms of data release in order to maximize research access when threats of disclosure warrant stronger protections. Restricted use contractual data, site licenses, and secure data enclaves are vehicles for allowing access to identifiable data under strong guarantees of confidentiality.

Cross-Cutting Ethical Issues

The above discussion of ethical considerations, through the lens of the methods used in behavioral and social science research,

emphasized issues of consent, privacy and confidentiality, and risk and harm. There are two other cross-cutting issues—deception and incentives—that merit additional consideration because they speak to the autonomy of human participants to determine whether to be part of research. Deception is best understood in the broader context of the amount of information available to research participants and at what point information is revealed consonant with ethical considerations. Incentives, too, have ethical implications because undue incentives may alter or influence the actual autonomy that research participants experience.

Deception

The provision of information about the nature and purposes of the research is intended to be respectful of the autonomy of persons to decide if they wish to be involved in a study and to allow them to make a meaningful decision. There has been a great deal of discussion and debate about the appropriateness of deception—providing misinformation—and the relationship between deception and partial or delayed information about the research. Willingness to participate in research and consent to do so require that research participants understand what they are being asked to do, even if they do not know at the outset the full purpose of the research. As summarized by Sieber,[104] typically researchers using deception seek to do the following: enhance stimulus control or random assignment; study responses to low-frequency events; obtain valid data without serious risk to subjects; or produce data that would otherwise be unobtainable. When deception is used, it is accompanied by debriefing at later stages of the study to inform participants about the fuller purposes of the research.

In *Planning Ethically Responsible Research,* Sieber allowed for the potential use of deception but considered alternatives including simulation studies and role playing.[104] She also set forth options in which information is concealed, but deception does not need to occur. These included informed consent to participate in one of various conditions, consent to be deceived, and consent to waive the right to be informed. The emphasis of these options is to gain agreement to participate, while making research participants aware that information about the study may be incomplete or inaccurate as an essential part of the work.

Federal regulations do allow the use of deception in research. Section 46.116(a)(1) of the federal regulations requires that participants be provided with a statement regarding the purpose of the research and the procedures involved. Yet Section 46.116(d) permits an IRB to waive elements of informed consent (even informed consent altogether) provided the IRB finds and documents that:

1. The research involves no more than minimal risk to the subjects;
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. The research could not be practicably carried out without the waiver or alteration; and
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.[6]

Importantly, the regulations attempt to balance the risks to participants (e.g., allowing deception waivers only in minimal risk research that does not affect the welfare of the participants) with the need to understand how human beings behave. For example, an investigator may be interested in examining the effects of mood on memory. Informing participants of the purpose of the study would defeat its purpose. Such a full disclosure, for example, might tell participants something like this:

> In this study, you will first watch a videotape of either a happy or sad film in order to put you in a good or bad mood. Then you will see a list of words that you will rate on a pleasantness scale. We don't really care about the ratings but we want you to think about the words. Then you will do some math computations that we really don't care about either, but we need some time to pass for you to forget some of the words. Then we will test your memory for the words. We are trying to discover the relationship between mood and memory for items that have the same or opposite feeling as the mood you are in.[113]

Instead of such a frank and self-defeating disclosure of the study's aims, a researcher could inform the participant about the procedures involved and any risk associated with those procedures, and something about the overall goals of the study (i.e., to better understand memory), leaving the explanation of the full purpose until later in the study.

It is important to note that deception in research can be used only if the research procedures pose no more than minimal risk and if the information cannot practicably be obtained in another way. In addition, the investigator must make a case to the IRB and obtain its approval before deception (or delayed disclosure) may be used in research. The federal regulations, the principles articulated in the Belmont Report, and professional codes of ethics provide a framework for the investigator and IRB members when evaluating the risk and benefit to participants. Irrespective of the methodology, evaluating the sensitivity of the study topic and participant vulnerability can assist investigators and the IRB in determining whether a waiver of informed consent is appropriate.

Allowing the use of deception within ethical boundaries can yield important insights into human behavior. Indeed, in both biomedical and social science research involving experimentation, participants typically are not informed whether they will participate in the treatment or the control/placebo condition. Deception used for the purpose of gaining an individual's participation in research or obtaining information that participants do not wish to divulge is, however, outside of the boundaries of ethical research.

Incentives

Incentives should compensate participants for their time and serve as a means to thank them for participating, but must be structured such that they do not coerce participation. Researchers should consider when to pay participants, how often payments are to be made, how much of an incentive to provide, and what the meaning of the incentive is. Incentives can be financial or nonfinancial (gift certificates, provision of a service), and the type of incentive may have different meaning for different groups of people. For example, a $10 payment in cash may not be excessive in the United States, but may be so in a developing country. A lottery ticket may be an appropriate, inadequate, or excessive incentive depending on a participant's knowledge regarding the odds of winning. Similarly, deferring all payments until the end of the study may encourage participants to continue to expend the time, but it could also induce participants to complete a study when they would otherwise prefer to terminate their participation. Smaller

incentives throughout the study might provide the right balance and decrease participant vulnerability.

In some instances, group-based incentives may be more appropriate. For example, when studying student behavior in a classroom, it may be more ethical to provide incentives to the entire class, rather than individual students. In this way, all students benefit, even those who do not wish to participate. In addition, when studying groups of any size, researchers must be aware that the decisions of a few (especially a vocal or popular few) may have a significant impact on others' decisions to participate (probably of most concern when studying adolescents). Although some degree of peer influence is probably acceptable, the researcher must consider whether the pressure to participate is a factor in the group process.

It is important to consider that incentives may be needed in order to ensure that the study population is sufficiently representative of the larger population from which participants are drawn. Just as vulnerable populations may be overincluded in studies because they are readily accessible or easier to manipulate, some populations may be underincluded because they do not have the wherewithal to travel to a research site, donate their time, or find the help they need with child care or elder care in order to participate. Incentives can serve to adjust for such imbalances. Because researchers are ethically obligated to ensure that the sample size is adequate for the research, incentives may ensure that the research as a whole is not undermined. Finding the right balance for encouraging, but not coercing, participation may not be easy, but it is ethically necessary.

Evolving Challenges

At any point in time, new scientific issues and methodological and technological advancements can raise ethical considerations in the conduct of human research that are uncharted, ambiguous, or controversial. As in the biomedical sciences, behavioral and social sciences face new ethical challenges, or understand old challenges differently, in the course of advancing knowledge in these fields. In our prior discussion of the use of observational methods in behavioral and social sciences research, for example, we raised issues regarding how investigators' use of video recording devices in public places, even when there is otherwise no interaction or intervention, changes the research from exempt to classified as human subjects research, as defined by 45 CFR 46, because recorded data are more readily identifiable. When new challenges first surface, ethical issues can seem formidable; typically, however, they become more tractable as scientists and those with expertise in the ethics of research unpack issues of risk of harm, privacy and confidentiality, and requirements of consent or the appropriateness of its waiver. A few illustrations make this point.

Internet Research

The Internet has expanded opportunities both to conduct research (e.g., surveys, experiments) and to study online behavior and human interaction. Earlier, we noted some of the complexities involved in using observational methods in the context of Internet chat rooms and considered the potential intrusiveness of such observation as well as the conditions under which Internet behaviors might be considered public or private. The Internet permits research on a global scale using extant data sources, using the Internet as a tool to collect data, and using the Internet context to study behavior in real-time and from web-based archives (e.g., transaction logs). Although the rapid transmission of information across time and space increases the salience of ethical considerations, the ethical issues that need to be weighed are not in general unique to Internet research.

Some Internet-based research presents few human research protection issues at all. If the data already exist as public records, there may be issues of appropriate reporting, but research on such records would typically fall outside of the regulatory definition of research with humans. In other instances, using the Internet to conduct research involves human research protection issues, including consent, confidentiality, and a weighing of benefits and risks. For example, when research is being conducted online, is awareness and continued participation a sufficient indicator of consent? Are there times when the sensitivity of the inquiry requires affirmative agreement to participate (for example, activating a radio button)? How can consent be documented especially given preferences for online anonymity and the frequent online use of pseudonyms? Are there areas in which Internet technology could increase risk (e.g., sharing of e-mail accounts, saving of documents by service providers)? And, do confidentiality protections need to be strengthened given the sensitivity of the data and the possibilities of compromising data security during data transmission or storage?

Internet technology also opens up new opportunities to study human behavior or interaction online. The nature of the Internet environment being studied; whether it might be presumed to be public or private (e.g., the rules governing the listserv, chat room, or discussion board); whether consent can or will be obtained; whether the confidentiality of the information can be protected (e.g., password protection for computers, encryption of data); and even how much the researcher reveals about her or his identity or presence all come into play in the ethical design and implementation of such research. The boundary between public and private is a particularly complex determination to be made in studying Internet communities, but rules of thumb are already being articulated to permit ethically responsible research in this environment (e.g., whether registration is required to be part of the forum; how many participants are in the forum; what are participants' perceptions of privacy).[114]

Most helpful in this rapidly emerging area of research on the Internet are the issues raised for investigators and for IRBs in reports by the American Association for the Advancement of Science (AAAS)[115] and the American Psychological Association (APA).[116] The AAAS and the APA reports point out the opportunities of using and collecting data and studying human interaction on the Internet. The AAAS report also addresses the basic principles of conducting human subjects research (e.g., informed consent, benefits and risk, privacy and confidentiality) in the context of this technology and also offers recommendations for undertaking research on the Internet and for undertaking studies and education that can further advance knowledge about human research ethics. The APA report, too, examines the benefits and challenges of conducting research on the Internet and provides advice on a wide-ranging set of issues from identifying potential harms and debriefing procedures to taking precautions when dealing with research involving minors.

Geospatial Measurements and Other Tracking Methods

In recent years, technological advancements in remote sensing and global positioning systems have permitted fine-grained geospatial measurements of latitude and longitude coordinates that allow for new and important studies of individuals over time and space.[117] Geospatial data on individuals' residences, workplaces, schools, or other locations are being linked with social surveys and other forms of social, environmental, and health data to study a range of issues from the distribution or transmission of disease[118] to how use of time is affected by travel and mobility patterns between locations.[119] Such data have enormous scientific potential, but also have embedded in them considerable potential for personal identification. In addition, unlike identifiers like name or Social Security number that can be more readily stripped from data sets, geospatial coordinates are themselves important data that can help to explain important behaviors and interactions and thus need to be preserved at some fine-grained level (even after statistical manipulation and masking) in order to remain of use.

As geospatial research has progressed, behavioral and social scientists are giving considerable attention to the ethical issues involved in working with such data aligned with other social data and how to maximize the scientific benefits of using this information while protecting the privacy of research participants or the confidentiality of the information obtained.[120] Primary data producers and researchers are addressing issues of consent and confidentiality at the data acquisition stage, and they and secondary users are examining the specification of strong data disclosure plans and strategies that can allow for meaningful data use while protecting data confidentiality. Because highly sensitive data can be involved, licensing agreements, enclaves that provide restricted access, and other mechanisms that maximize use yet minimize risk are being assessed by the behavioral and social science research community, including, in 2006–2007, the National Academies' Panel on Confidentiality Issues Arising from the Integration of Remotely Sensed and Self-Identifying Data.[121]

Although advanced technologies allow for the collection and preservation of very large amounts of geospatial measurements over large spans of geography, the ethical issues of confidentiality and risk reduction are akin to those that the behavioral and social sciences have been considering about microlevel data linkages for over a decade.[122] Even in this context, much research using such measurements is of minimal risk (depending upon the nature of the inquiry and the strength of the data protection plan). Yet behavioral and social scientists working in this milieu are giving considerable attention to how best to protect confidentiality and promote data use.

Beyond geospatial measurements, there are other new technologies for tracking behavior that have scientific potential for studying human interaction and social exchange. Some investigators have research participants use wearable computers to study how social relationships build and networks are formed. Sensor devices in computers permit recording sound, movement, and geographic locations with essentially continuous, fine time resolution for long periods of time over potentially large samples.[122,123] Researchers working in this domain are addressing both privacy and confidentiality concerns (for example, they intend to reduce privacy concerns by focusing on the patterns of talk and not the content of the talk). Some of the mechanisms being considered and honed for addressing privacy and confidentiality issues with geospatial data would have obvious relevance here.

Third Parties

The very nature of behavioral and social science research aims to understand how people act in their social contexts. For example, in order to fully comprehend the initiation and maintenance of drug use by young adults, a researcher may ask research participants about relationships with friends and family; contacts with social institutions such as a social or academic club, sports organization, or church; the strength of these associations; and the quality of social networks and relationships. The goal of such questions is to understand humans and their life circumstances, even though, in so doing, information about others is gathered from research participants in order to gain a more complete picture of these person's lives.

In 2001, a controversial case raised questions about the status of this information. The case, involving an adult daughter who provided a personal health history that included information about her father, raised questions about the appropriateness of providing this information without the father's consent. The term *third party* was used in this context to refer to the father, someone who was referenced by a research participant. Irrespective of particular aspects of this incident, the issue that became high profile was whether those who are referenced become research participants because someone in the study provided personal, identifiable information concerning them. The crux of the debate was about whether such persons met the regulatory definition of human subjects, and thus were entitled to the protections afforded by informed consent (unless a case is made for its waiver).

There is good reason to protect personal information provided by research participants—whether it is only about themselves or in relation to others in their social sphere. There is also good reason in terms of the integrity of research process and trust in science, as well as commitments to human participants, to be circumspect about alerting the identified human subjects in research. First, human subjects may be at increased risk if the fact of their participation in a study is known (e.g., study of victims in abusive marriage)—a necessity if third parties were required to give consent. Second, revealing participation of human subjects to others intrudes upon research participants' privacy and the confidential nature of information provided during the course of research. Thus, care must be taken to ensure that the rights of and responsibilities to human subjects are not compromised or eclipsed in considering whether consent from third parties should be sought.

The National Human Research Protections Advisory Commission (NHRPAC)[125]—the first advisory committee established in 2000 by then DHHS Secretary Donna Shalala to advise the Office for Human Research Protections—provided in our view sound recommendations about third parties, although the issue still remains unresolved. The NHRPAC clarification states that "neither reference to a third party in a research design, nor the recording of information about a third party in research records suggests that a third party must be regarded as a research subject." NHRPAC allowed for the possibility that third parties might be human subjects, but saw this determination to be a dynamic one

to be made by IRBs based on the substance of the research and not on the fact that personal information provided by research participants may also be considered personal information relevant to others.

In locating the determination with IRBs, the NHRPAC statement makes clear that third parties who are referenced in research are not necessarily considered human subjects but that third parties may become human subjects if the IRB, through careful analysis of a number of factors, determines that the focus of the research is really also on the third party and not on (or not only on) the designated human subject. NHRPAC's statement also makes clear that the requirement of consent, or waiver of consent, pertains only to human subjects of research as defined by 45 CFR 46, and not to third parties unless IRBs determine that these third parties are human subjects as well.

Although this issue remains unresolved from a federal regulatory point of view, the thrust of the NHRPAC recommendation is compatible with the general emphasis on individuals as human research participants in 45 CFR 46, delegating to IRBs the final determination in contested or highly ambiguous circumstances as to when multiple parties are the subjects of research. In behavioral and social science research, multiple parties or groups (e.g., studies of gangs, work teams, governance boards) may be the subjects of research. Couples and family research, for example, can raise complex issues regarding privacy, confidentiality, and consent accorded to each individual while still being respectful of the family unit under study.[126] Thus, behavioral and social scientists have experience in protecting multiple human subjects under circumstances where more than one party is the subject of the research.

Conclusion

There is no doubt that new research questions, contexts of study, or technologies will raise new questions and challenge the best of investigators' ethical judgments. To develop researcher savvy on ethical issues, it remains important to include training in ethics and human research protection as an integral part of research training. It is also important to foster the empirical study of ethical issues so that decisions about consent, risk perception, potential for harm, strategies for risk reduction, and so forth can be assessed based on meaningful data. Ethical decision making is an ongoing, dynamic process that can require of researchers and research fields extrapolation and translation of ethical principles to addressing new research questions, examining new or rapidly changing circumstances or contexts for research, or using new research capacities. To the extent that behavioral and social scientists embed ethical considerations in the ongoing design and implementation of methods, they can achieve the dual goals of advancing science and protecting human participants in their work.

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