Unparalleled growth in psychological science beginning in the 20th century has and will continue to make significant contributions to society’s understanding of biological, cognitive, emotional, cultural, and social processes characterizing and influencing adaptive and maladaptive behavior of individuals and groups as well as the extent to which interventions and policies succeed in promoting the development of persons and organizations, preventing risk, and remediating psychological disorders and social problems. Increased public recognition of the value of social research has been accompanied by heightened sensitivity to the obligation to conduct social science responsibly. The formidable task of ensuring ethical competence in psychological research depends on sensitive and informed planning by scientists who possess the ethical commitment, awareness, and competence to ensure that research meets the highest principles of scientific design and human participant protections.

This chapter provides a broad overview of organizational and federal guidelines governing the responsible conduct of psychological research. We begin with discussion of fundamental requirements for ethical decision making for psychological science incorporating a goodness-of-fit ethics perspective (Fisher, 2002a, 2003a; Fisher & Goodman, 2009; Fisher & Masty, 2006; Fisher & Ragsdale, 2006). Major portions of the chapter address six major domains of research ethics responsibilities: institutional review board (IRB) review, informed consent, confidentiality, deception research, conflict of interest, and reporting conflict of interest. (More information on ethical issues with vulnerable populations can be found in Chapter 17 of this volume; on Internet research in Chapter 18 of this volume; on deception research in Chapter 19 of this volume; and on research involving animals in Chapter 20 of this volume.)

A significant portion of the chapter addresses informed consent issues because the requirements of informed consent encompass descriptions of many essential participant protections required by law and the profession of psychology. These protections include discussion of research risks and benefits, research compensation, voluntary participation, and special considerations for children and adults with questionable capacity to consent, as well as when it is ethically appropriate to dispense with part or all of informed consent requirements. Details on the relevance of the Health Insurance Portability and Accountability Act (HIPAA; 1996) to the conduct of research creating, using, or disseminating protected health information is also provided. We conclude the chapter with an illustration of how the goodness-of-fit ethics framework can enhance the responsible conduct of multicultural research.
ETHICAL DECISION MAKING AND THE RESPONSIBLE CONDUCT OF RESEARCH

The Ethical Principles of Psychologists and Code of Conduct (the Ethics Code; American Psychological Association [APA], 2010a) and the Code of Federal Regulations (C.F.R.) Protection of Human Subjects (Department of Health and Human Services [DHHS], 2005) provide a set of aspirational principles and behavioral rules written broadly to apply to researchers’ varied roles and the diverse contexts in which research is conducted. In their everyday activities, research psychologists will find many instances in which familiarity with and adherence to specific regulations and Ethical Standards provide adequate foundation for ethical actions. There will also be many instances in which (a) the means by which to comply with a standard are not readily apparent, (b) two seemingly competing standards appear equally appropriate, (c) application of a single standard or set of standards appears consistent with one aspirational principle but inconsistent with another, or (d) a judgment is required to determine whether exemption criteria for a particular standard are met. This section discusses ethical attitudes and decision-making strategies that can help psychologists prepare for, identify, and resolve ethical challenges as they continuously emerge and evolve in the conduct of research.

Ethical Commitment

Ethical commitment refers to a strong desire to do what is right because it is right (Josephson Institute of Ethics, 1999). In psychology, this commitment reflects a moral disposition and emotional responsiveness that moves research psychologists to creatively apply the federal regulations and the Ethics Code principles and standards to the unique ethical demands of the scientific context (Fisher, 2012). The desire to do the right thing often has been associated with moral virtues or moral character defined as a disposition to act and feel in accordance with moral principles, obligations, and ideals—a disposition that is neither principle bound nor situation specific (Beauchamp & Childress, 2001; MacIntyre, 1984). Virtues necessary for the conduct of responsible research are dispositional habits acquired through social nurturance, education, and science mentoring that provide psychologists with the motivation and skills necessary to apply the ideals and standards of psychological science (Fisher, Fried, & Feldman, 2009; Fisher, Fried, Goodman, & Kubo Germano, 2009; Fisher, Wertz, & Goodman, 2009; Jordan & Meara, 1990; National Academy of Sciences, 1995).

For disciplines such as psychology, in which regulations and organizational guidelines for research dictate the general parameters but not the context-specific nature of ethical conduct, ethical commitment is reflected by behaviors stemming from the virtues of conscientiousness, discernment, and prudence (Fisher, 2012). A conscientious researcher is motivated to do what is right because it is right, diligently tries to determine what is right, and makes reasonable attempts to do the right thing. A discerning investigator brings contextually and relationally sensitive insight, good judgment, and appropriately detached understanding to determine what is right. And a prudent scientific psychologist applies practical wisdom to ethical challenges leading to right solutions that can be realized given the nature of the problem and the participants involved.

Ethical Awareness

Ethical commitment is just the first step in effective ethical decision making. Good intentions are insufficient if psychologists fail to identify the ethical situations to which they should be applied. Conscientious psychologists understand that identification of situations requiring ethical attention is dependent on familiarity and understanding of relevant federal guidelines and organizational codes of conduct applicable to their specific work-related activities. Too often psychologists approach ethics as an afterthought to research designs. Ethical planning based on familiarity with virtues, foundational principles, ethical standards, professional guidelines, state and federal laws, and organizational and institutional policies should be seen as integral rather than tangential to psychologists’ work.

Familiarity with the rules of conduct set forth in regulation and the Ethical Standards enables psychologists to take preventive measures to avoid the harms, injustices, and violations of participant rights and...
inadequate protection of their welfare. Another important element of information gathering is identifying and understanding applicable laws, government regulations, and institutional and organizational policies that may dictate or limit specific courses of actions necessary to avoid or resolve an ethical problem.

**Goodness-of-Fit Ethics**

Ethical commitment and well-informed ethical planning will reduce but not eliminate ethical challenges that emerge during the course of research. Ethical problems often arise when two or more principles or standards appear to be in conflict, from unforeseen reactions of participants, or unexpected events. There is no ethical menu from which the right ethical actions can simply be selected. Many ethical challenges are unique to time, place, and persons involved. The very process of generating and evaluating alternative courses of action helps place in vivid relief the moral principles underlying such conflicts and stimulates creative strategies that may resolve or eliminate them.

Goodness-of-fit ethics (Fisher, 2002a, 2003a; Fisher & Goodman, 2009; Fisher & Masty, 2006) conceptualizes research vulnerability (participant susceptibility to research risk) as the joint product of participant characteristics and the research context. From this perspective, harms produced by participant–research interactions can be minimized by fitting ethical procedures to participant susceptibility to or resilience against research harms. Goodness-of-fit ethics involves dual attention to characteristics of participants and the research context that may conjointly create or exacerbate research vulnerability. Such analysis is followed by exploration of alternative approaches to shaping the research design and ethical procedures that will maximize scientific advancement and the protection of participant and social welfare (Fisher & Ragsdale, 2006). To identify and minimize risks emerging from the intersection of population and research characteristics, the goodness-of-fit approach encourages investigators to ask three questions: What special life circumstances may render participants more susceptible to risks that arise in this research design? What aspects of the methodology, implementation, or dissemination may create or exacerbate such research risks? And, how can research procedures be fitted to participant characteristics to best minimize risk? (Fisher, 2003b; Masty & Fisher, 2008).

For example, in a recent study, Fisher (2010) drew on data on misconceptions about and mistrust in HIV vaccine clinical trials among intravenous drug users (IDUs) to develop procedures that could enhance consent preparedness of this population. IDUs account for almost one third of HIV/AIDS cases in the United States (Centers for Disease Control and Prevention, 2009). When designing HIV vaccine clinical trials, investigators must consider both the potential benefits to the IDU population of research leading to the discovery of an effective HIV vaccine and the characteristics of this population (e.g., lack of education, health care disparities, social stigma) that require special ethical considerations for ensuring informed, rational, and voluntary consent. Fisher (2010) created and empirically evaluated the effectiveness of a brief, pictorially illustrated, population-sensitive lesson on the purpose and nature of HIV vaccine trials that specifically addressed issues of concern to the IDU population. She found that exposure to the lesson significantly increased IDUs' knowledge of inclusion criteria, random assignment to placebo, likelihood of false-positive HIV test results, and the experimental blind and reduced misconceptions that the vaccine can cause participants to acquire or transmit HIV. In addition, although not directly addressed in the lesson, exposure significantly increased IDUs' trust in investigators and sponsors of these trials.

**Colearning**

Colearning is a goodness-of-fit process whereby perspectives from the prospective participant populations are used to identify ethical issues and construct ethical procedures (Fisher, 1999, 2002b). It enables researchers to fit research methods and ethical procedures to the needs and values of the participant population (Fisher & Ragsdale, 2006) and assumes that ethical decision making may be inadequate if it fails to consider the views of participants or their representatives (Fisher, 1999, 2000b, 2002a). A second substantive assumption of colearning is that researchers, participants, and participant communities have
equally important but different expertise in areas that are essential to the conduct of responsible science. Although researchers have expertise in the extant research literature and the research methods that can be utilized to study public health concerns, prospective participants and their community representatives have expertise in what they think is important to study, how they will react to planned procedures, the subjective risk–benefit balance of the research, and the moral and cultural frameworks informing their perspectives (Fisher, 1997, 1999, 2000b; Fisher & Goodman, 2009; Stiffman, Freedenthal, Brown, Ostmann, & Hibbeler, 2005).

As important as gaining participant perspectives is to the development of population-fitted ethical procedures, these perspectives must inform, but cannot substitute for, the ethical decision-making responsibilities of psychological scientists. Participant opinions help to bring into practical application aspirational moral principles and behavioral guidelines in research procedures that reflect the values and merit the trust of participants (Fisher, 2000a). We next turn to specific domains of ethical awareness essential to the responsible conduct of psychological science.

INSTITUTIONAL APPROVAL AND THE RESPONSIBLE CONDUCT OF RESEARCH

The responsible conduct of psychological research depends on ethically informed planning by psychologists and careful review by federally mandated IRBs. The National Research Act of 1974, Public Law 93-348, mandates that universities receiving federal funding for biomedical or behavioral research must establish an IRB. Codified in Title 45, Part 46 of the C.F.R. (DHHS, 2005), IRBs must ensure that federal regulations are met and that research participants’ rights and welfare are protected. Institutions with IRBs found to be in non-compliance with regulations can lose federal funding for both their research and student programs. The diversity of expertise and wide latitude in decision making given to individual IRBs under federal regulations can be intimidating to psychologists who must gain IRB approval before conducting their research (Standard 8.01, Institutional Approval; De Vries, DeBruin, & Goodgame, 2004; DuBois, 2004; Eisenberg et al., 2004). As a first step in developing IRB applications, psychologists should familiarize themselves with federal regulations and the Office of Human Research Protection’s (n.d.) “Frequently Asked Questions” website.

Moral Principles Guiding Institutional Review and Psychological Science

IRBs are charged with ensuring that investigators protect the rights and welfare of research participants. Specific IRB requirements reflect three general moral principles articulated by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1979) and adapted in three corresponding aspirational principles within the APA Ethics Code (Principles A, Beneficence and Nonmaleficence; Principle D, Justice; and Principle E, Respect for People’s Rights and Dignity). Beneficence and nonmaleficence requires IRBs to ensure that research submitted for their review is designed to maximize benefits for science, humanity, and research participants and to avoid or minimize risk or harm. Applied to the research context, the principle of justice obligates IRBs to ensure that investigators will equitably select individuals to participate in research and that the potential benefits and costs of research participation are distributed fairly among diverse groups. Principle E, Respect for People’s Rights and Dignity, requires IRBs to ensure that in research protocols submitted for review, informed consent and confidentiality procedures protect the autonomy and privacy rights of participants.

Scientific Validity and IRB Risk–Benefit Calculation

A common error made by social behavioral investigators submitting protocol applications for IRB review is omitting an explanation of the scientific justification for the study on the basis of the erroneous assumption that IRBs are not responsible for evaluating scientific merit. Although IRBs should never take on the role of a scientific peer review panel, they are obligated to evaluate the balance of potential research benefits to risks. Because a study that lacks methodological validity cannot provide
scientific or social benefits, a research protocol that poses even minimal risk may not be approved if an IRB has no evidence that the design has scientific merit (Fisher & Rosendahl, 1990). Psychologists can facilitate approval of their protocols by including in their IRB applications brief explanations of the scientific justification for their selection of research questions, methods, and participant populations (Fisher, 2002b, 2012).

APA Ethics Code Requirements for Institutional Approval

Standard 8.01, Institutional Approval, of the Ethics Code (APA, 2010a) has four basic requirements. First, psychologists must know if and from whom institutional approval is required. All institutions receiving federal funding for biomedical or behavioral research are required to establish IRBs to protect the rights and safety of research participants. In addition, many social welfare agencies, health care facilities, schools, correctional facilities, businesses, and other public and private organizations have their own internal review requirements for research. Psychologists conducting research in these settings may need to obtain approval from both their institutional IRB and the ethics review board for these sites. Federal guidelines list activities that are exempt from institutional review; however, the exempt status of any specific project must be approved by an institution’s IRB (DHHS, 2005). Depending on institutional policy, psychology laboratory course experiments may not require review (Fisher, 2012).

The remaining three requirements within the standard are that applications for institutional review must be accurate, approval must be obtained before the research is conducted, and research procedures must follow the approved protocol. Failure to meet any of these conditions violates this standard. It is not unusual for methods to be modified during different phases of research. Any changes in participant informed consent language or procedures, compensation, confidentiality protections, or methods that increase participant risk or safety should be resubmitted for institutional approval before implementation. Psychologists should consult the appropriate IRB about the need to provide an informative memo or to resubmit proposals for minor changes unrelated to participant protections or welfare.

Defining Minimal Risk

Risks associated with social–behavioral research often meet the federal definition of minimal risk (Citro, Ilgen, & Marrett, 2003; Fisher, Fried, & Feldman, 2009), yet this term is poorly understood by investigators and IRBs as evidenced by widespread inconsistency among different IRBs in applying the definition to evaluate the risk level of surveys and other methods commonly used in psychological research (Janofsky & Starfield, 1981; Shah, Whittle, Wilford, Gensler, & Wendler, 2004). Lack of consensus between IRBs and investigators on the level of risk not only presents barriers to expedited review, but also can result in informed consent language that overstates participation risk.

One reason for this confusion is the ambiguity of the regulatory language for the definition of minimal risk, which varies within the regulations depending on whether the research includes prisoners, children, or adults with impaired cognitive capacity. Another reason is that examples in federal regulations are drawn largely from biomedical research. Subpart A (known as the Common Rule) of federal regulations gives the following definition:

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. (DHHS, 2005, 45 C.F.R. § 46.102(i))

Federal regulations go into some detail describing when the collection of blood samples and other biological specimens should be considered minimal risk, but they provide no such detail on which types of routine psychological examinations or tests meet this criteria. This often leaves psychological scientists and their IRBs at odds in interpreting level of risk. As described by Fisher, Kornetsky, and Prentice (2007), the DHHS Secretary’s Advisory Committee for Human Research Protections (SACHRP;
Fisher and Vacanti-Shova

addressed this problem for research involving children by generating a list of routine procedures for the “well-child” pediatric visit and the pediatric mental health interview as reasonable benchmarks to determine routine medical and psychological examinations or tests. The well-child routine procedures cited in this report included questions regarding potential child abuse and family conflict for younger and older children and sexual and other health-compromising behaviors for adolescent patients (SACHRP, 2005). Investigators working with adults might find it useful to generate an equivalent list to determine minimal risk benchmarks for this population.

Even when biomedical examples are provided in federal regulations, IRBs and investigators often are unsure whether assessment of minimal risk must be limited to these specific examples or other procedures judged to be equivalent. Among the criteria identified by SACHRP for determining minimal risk equivalence are (a) the duration and frequency of the procedure, (b) the cumulative risk posed by a set of procedures that individually might be equivalent but cumulatively be greater in probability or magnitude of risk than those in daily life or routine physical or psychological examinations, and (c) the degree to which any harms if they do occur are transient and reversible (Fisher et al., 2007; Institute of Medicine [IOM] of the National Academies, 2004; SACHRP, 2005).

Exempt Research and Expedited Review
Federal regulations 45 C.F.R. § 46.101(b)(1–6) (DHHS, 2005) detail a narrow range of research with human participants that are exempt from required IRB review. Psychologists seeking to apply for such an exemption should remember that the determination of whether a study meets the criteria for exempt status is the responsibility of the IRB and not the individual investigator. Thus, investigators must submit to the appropriate IRB a formal request and justification for exempt status.

Federal regulations also permit IRBs to conduct an expedited review when the research protocol submitted is judged to present no more than minimal risk to participants or entails minor revisions in an already approved protocol (DHHS, 2005, 45 C.F.R. § 46.110). When meeting expedited review criteria, the evaluation may be carried out by the IRB chair or designee in lieu of full board review. Most psychological studies meet these criteria, but in the perception of many in the social and behavioral science research community, IRBs often overestimate social behavioral research risks and thus fail to expedite protocols that meet the federal criteria (National Research Council, 2003). Applying the regulatory definition of minimal risk has been confusing for IRBs and investigators alike (Fisher et al., 2007). One reason for this confusion is that federal guidance on expedited categories is short on examples of social behavioral research (DHHS, 1998). To facilitate expedited review of new IRB applications, psychologists should carefully document their rationale for why the research is minimal risk. For continuing review applications, psychologists should detail how the research plan for the coming year does not differ in significant ways in the procedure and in the protections for human participants that previously were IRB approved.

Justifying Treatment and Control Conditions: Clinical Equipoise
Important questions of treatment efficacy and effectiveness driving the conduct of randomized clinical trials for mental health treatments raise, by their very nature, the possibility that some participants will fail to respond to treatment conditions or experience a decline in mental health during the trial. The ethics of intervention research requires clinical equipoise—genuine uncertainty on the part of the scientific community regarding the comparative therapeutic merits of each arm in a clinical trial. IRBs generally will not approve research if either a treatment or control condition has been empirically substantiated as inferior. This does not exclude psychologists from conducting studies that seek to test new treatments for non-responders to empirically validated interventions, to improve upon existing treatments, to study the practical effectiveness of interventions validated under highly controlled conditions, or to study the generalizability of validated treatments to unstudied populations (Fisher, 2012). IRBs do expect investigators to provide evidence explaining why they believe
(a) participants placed in a control group will not be deprived of an available treatment with empirically validated effectiveness, and (b) individuals assigned to the experimental intervention will not be exposed to greater risk than if they had been assigned to a control or standard treatment condition.

To comply with IRB requirements to minimize risk and Ethics Code Standard 3.04, Avoiding Harm, research psychologists should develop procedures to identify and address the possibility of nonresponders to the treatment condition or those who experience a decline in mental health during a clinical trial. Such steps can include (a) scientifically and clinically informed inclusion and exclusion criteria for patient participation; (b) the establishment of a data safety monitoring board to evaluate unanticipated risks that may emerge during a clinical trial; and (c) before the initiation of the research, establishing criteria on the basis of anticipated risks for when a trial should be stopped to protect the welfare of participants (Fisher, 2012).

Ensuring Consent to Research Is Informed, Rational, and Voluntary

Within the context of research, informed consent requirements reflect Ethics Code Principle E, Respect for People’s Rights and Dignity. Guided by this aspirational principle, psychological scientists must ensure that decisions to participate in research are informed, voluntary, and rational. The specific Ethics Code standards applying to informed consent for research are consistent with federal regulations for the Protection of Human Subjects (DHHS, 2005, 45 C.F.R. § 46.116). With few exceptions, psychologists must obtain and document written or oral consent in the manner set forth in Ethics Code Standard 3.10, Informed Consent, and Standard 8.02, Informed Consent to Research.

Language and Terminology

The informed component of consent requires that individuals are provided all the pertinent information needed to make a reasoned choice about whether they wish to participate in a study. This includes providing information in a language and at a language level understood by prospective participants and, where applicable, their legally authorized representative (Standards 3.10(a) and 3.10(b)). For example, psychologists must use appropriate translations of consent information for individuals for whom English is not a preferred language or who use sign language. Psychologists also should adjust reading and language comprehension levels of consent procedures to an individual’s developmental or educational level or reading or learning disability. When obtaining guardian permission and participant assent for research involving populations that do not speak English or for whom English is a second language, psychologists should be alert to the possibility that prospective participants and their legal guardians may have different language preferences and proficiencies (Council of National Psychological Associations for the Advancement of Ethnic Minority Interests, 2000; Fisher et al., 2002).

Recently immigrated individuals or those from disadvantaged communities may lack familiarity with assessment, treatment, or research procedures, as well as with terminology typically used in informed consent documents. These individuals also may be unfamiliar with or distrust statements associated with voluntary choice and other client–patient or research participant rights described during informed consent. Standard 3.10 requires sensitivity to the cultural dimensions of individuals’ understanding of and anticipated responses to consent information and mandates psychologists to tailor informed consent language to such dimensions. This also may require psychologists to include educational components regarding the nature of individual rights in agreeing to psychological services or research participation (Bruzzese & Fisher, 2003). For individuals not proficient in English, written informed consent information must be translated in a manner that considers cultural differences in health care or scientific concepts that present challenges for a word-for-word translation. When using interpreters to conduct informed consent procedures, psychologists must follow the requirements of APA Standard 2.05, Delegation of Work to Others in assuring their competence, training, and supervision.

Consent via Electronic Transmission

Standard 3.10(a) requires informed consent be obtained when research is conducted via electronic
transmission, such as the telephone or the Internet. Psychologists need to take special steps to identify the language and reading level of those from whom they obtain consent via electronic media. In addition, psychologists conducting research via e-mail or other electronic communications should take precautions to ensure the individual who gave consent is in fact the individual participating in the research, for example, use of a participant–client–patient password (Fisher, 2012). (More information on this subject can be found in Chapter 18 of this volume.)

Consent for Recording Voices and Images in Research
Under Ethics Code Standard 8.03, Informed Consent for Recording Voices and Images in Research, psychologists must obtain informed consent to electronically recorded research participation before beginning data collection. Stored auditory and visual records pose a greater risk of personal identification over time than other data formats, and therefore consent procedures must allow persons to evaluate the personal consequences of such risks before research participation. Restricting data access to the research team best protects personal identification. If recordings also will be used for training purposes or presentation at professional meetings, consent must be obtained specifically for these purposes unless image scrambling, voice distortion, or other identity-masking techniques can ensure adequate disguise.

Describing the Nature of Participation
Prospective participants, and when appropriate their legal guardians, must be given information and the opportunity to ask questions about the purpose, duration, and procedures involved in participation that is sufficient to make an informed decision.

Qualitative Data Collection
The open-ended nature of ethnographic, phenomenological, and participant observation studies can make it difficult to anticipate the exact nature of information that may be gained through participant–investigator interactions. The focus on discovering emergent themes in qualitative research means that investigators do not always know beforehand privacy and confidentiality issues that may emerge during the course of research (Fisher, 2004a). Investigators should alert the prospective participant to this possibility during informed consent, monitor verbal or behavioral information during the course of the study, and remind the participant about confidentiality protections and limitations when unexpected topics emerge. If a new direction of inquiry emerges that might be in conflict with participants’ confidentiality expectations, this should be identified and the participant given the opportunity to reconsent. In street studies involving drug use or other illegal behaviors, an agreement can be reached during informed consent about which activities will and will not be asked or witnessed (Fisher, 2012; Singer et al., 2000).

Explanation About Control Groups and Methods of Assignment to Treatment Conditions
The principles of good scientific design often require investigators conducting intervention research to (a) assign some participants to control group conditions as a point of comparison for the experimental treatment (between-group designs) or (b) vary the treatment and control conditions for individual participants (within-group designs). Control conditions may consist of participants receiving different levels of the investigational intervention, a treatment of documented effectiveness, currently available services (treatment-as-usual), a placebo, or no treatment. Provisions No. 2 and No. 3 of Ethic Code Standard 8.02b, Informed Consent to Research, require that informed consent adequately describes the nature, potential risks, and probable benefits of control group assignment as well as how assignment to experimental and control group conditions will be made. When appropriate, the nature of random assignment should be explained using terminology that can be understood by individuals unfamiliar with the scientific method. Informed consent for studies using single- or double-blind procedures should describe the extent to which participants and members of the treatment and research teams will know which group the participant has been assigned to and the steps that will be taken to determine if and how the blind will be broken. From a goodness-of-fit perspective, effort should be made to
fit explanations about control group randomized designs not only to participants’ cognitive and educational characteristics but also to experiential differences, such as health disparities, that may influence their attitudes about the trustworthiness of the investigators (Fisher & Masty, 2008).

**Describing Research Risks**
Informed consent must provide an accurate description of the potential risks of research participation. In psychopharmacological research, such risks often are defined in terms of the range of side effects that might realistically occur determined on the basis of previous research. In intervention research, prospective participants must be informed about potential risks of assignment to each arm of a clinical trial. Because informed consent to randomization must by definition precede actual assignment to conditions, the consent process must include the realistic range of risks that might arise in assignment to either condition. When psychosocial questionnaires or therapies are added to a medical intervention, discussion of risks and benefits should be limited to those that may result from the research, as distinguished from risks and benefits of therapies patients would receive if not participating in the research (DHHS, 2005, 45 C.F.R. § 46.111(a)(2)).

**Describing Research Benefits**
For both therapeutic and nontherapeutic research, investigators need to distinguish those aspects of the research that may provide direct benefits to the participant and those procedures designed to produce potential benefits to scientific knowledge. In research involving children, federal regulations include as a direct benefit monitoring procedures that are likely to contribute to the participant’s well-being as potential benefits (DHHS, 2005, 45 C.F.R. § 46.4.05). Thus, when appropriate, psychologists can include in consent forms a description of direct benefits that may be derived from participation, such as (a) access to new treatments not yet available for general use; (b) benefits of the experimental treatment if it proves effective during or following the conclusion of the study; (c) comprehensive psychological assessment and monitoring; (d) treatment referrals; or (e) upon participant-signed authorization, a summary of the participant’s response to the treatment conditions forwarded to a qualified mental health professional. When it comes to describing benefits, psychologists need to be aware that the Office for Human Subjects Protections has interpreted federal regulations as prohibiting investigators from describing participant compensation as a benefit when obtaining informed consent (see Standard 8.06, Offering Inducements for Research Participation).

**Addressing the Therapeutic Misconception**
Appelbaum, Roth, and Lidz (1982) coined the term *therapeutic misconception* to describe participants’ common but incorrect beliefs about participation in randomized clinical trials: (a) that individualized needs will be taken into account in condition assignment, and (b) unreasonable expectations of medical benefit from research participation (see also Appelbaum, Lidz, & Grisso, 2004). These misconceptions may be compounded by therapeutic mistrust in underserved or marginalized populations (Fisher, Oransky, et al., 2008).

APA Standard 8.02b, Informed Consent to Research, also requires that psychologists address such potential misconceptions during informed consent (see Fisher, 2012). The first provision, clarifying the experimental nature of the treatment, requires that informed consent procedures address the general misconception that “experimental” treatment means “better” treatment with known direct benefits for participants. The primary goal of intervention research is to provide generalizable information on whether a particular type of intervention is successful. Depending on the stage of research, an untested experimental treatment may place participants at greater risk than a no-treatment or treatment-as-usual condition. Most important, psychologists must take reasonable steps to communicate to prospective participants that the purpose of conducting treatment research is to determine whether or not a treatment works or how it works in comparison with another treatment.

**Discussing Confidentiality**
In behavioral sciences, the greatest risk of research participation is often disclosure of confidential
information obtained during the course of research (National Research Council, 2003). Disclosure of confidential information can result in criminal or civil liability or financial or social damage. To ensure that prospective participants are fully informed, consent procedures must include a clear explanation of the extent and limits of confidentiality, including (a) whether investigators must comply with reporting requirements such as mandated child abuse reporting, elder abuse, or duty-to-warn laws; (b) the investigator’s confidentiality and disclosure policy for responses indicating a participant or another person is in immediate danger or otherwise at a high level of risk; or (c) if the method of data collection may limit the extent of confidentiality protections as may be the case when research is conducted via the Internet. Investigators conducting research in schools or studies involving children or adults with questionable consent capacities should familiarize themselves with evolving federal and state laws governing guardians’ rights of access to health- or school-related records created, used, or disclosed by a researcher (see Fisher, 2012), and they should disclose such information to guardians and children during informed consent. We address additional confidentiality obligations later in this chapter.

The Voluntary Nature of Participation

During consent, investigators must directly inform participants they will not be penalized for declining or withdrawing from participation, especially when the prospective participant has reason to believe that dissent may result in adverse consequences as indicated in APA Standards 8.02b and 8.04, Client/ Patient, Student, and Subordinate Research Participants. Institutionalized populations are particularly vulnerable to involuntary participation in research. Prisoners and youth held for brief periods in detention centers, for example, are highly vulnerable because of their restricted autonomy and liberty, often compounded by their low socioeconomic status, poor education, and poor health (Gostin, 2007). Incarcerated persons have few expectations regarding privacy protections and may view research participation as a means of seeking favor with or avoiding punishment from prison or detention guards or officials. Psychological scientists should be aware that federal regulations require additional protections against involuntary participation for prisoners (DHHS, 2005, 45 C.F.R. § 46, Subpart C) and institutionalized children (DHHS, 2005, 45 C.F.R. § 46.409). The requirement that the voluntary nature of participation is not only communicated to potential participants but also ensured within the research design is also relevant to requirements of APA Standard 3.08, Exploitative Relationships.

Compensation for Research Participation

Informed consent must accurately describe the nature of compensation (cash, monetary equivalents, services) as well as under what conditions participants will receive none, partial, or full compensation. Selecting noncoercive compensation for research participation helps ensure that participation is voluntary, that research burdens are not borne unequally by economically disadvantaged populations, and that these populations are not deprived (based on inability to afford to participate in the study) of knowledge generated by research that can be applied to enhance their well-being (Principle D, Justice). Psychologists considering compensation for effort, time, and inconvenience of research should take steps to ensure that inducements do not encourage individuals to lie or conceal information that would disqualify them from the research or lure them into procedures they otherwise would choose to avoid.

Ethics Code Standard 8.06, Offering Inducements for Research Participation, recognizes that some inducement often is necessary to ensure a sufficiently large and representative sample and that it is possible for investigators to distinguish between “due” and “undue” inducements (Dickert & Grady, 1999; Macklin, 1981). Some institutions adopt a standard compensation rate for all research participation. Others have defined noncoercive financial inducements as the amount of money a normal, healthy volunteer would lose in work and travel time or by fair market value for the work involved. Different economic and cultural circumstances may lead to varying perceptions of a cash inducement as fair or coercive (Fisher, 2003b; Oransky, Fisher,
Mahadevan, & Singer, in press). At the same time, fairness and justice entitle all persons to equal compensation for equal levels of participation in a particular research project (Ethics Code, Principle D, Justice). Consulting with members of the population who will be recruited for research participation about different types of research compensation can help investigators and their IRBs determine the extent to which cash or nonmonetary compensation is fair or coercive.

Providing psychological services as compensation for research participation is ethical when participants are fully aware of (a) the nature and risks of services (e.g., the type of treatment, the type of provider, risks to confidentiality), (b) the personal and financial obligations and time commitment involved in receiving the services, and (c) limitations of the type and in the length of services provided. Psychological scientists might also wish to refer to Ethics Code Standard 6.04, Fees and Financial Arrangements, and Standard 6.05, Barter With Clients/Patients. Linking involvement in nontherapeutic research with treatment that immediately follows may encourage participants with mental health problems to engage or continue in treatment. However, psychologists should take special steps to ensure that offering such services does not compromise the voluntary nature of research participation of individuals who do not have access to adequate health care and social services (Fisher, 2004a, 2012).

The conditions under which individuals will qualify for full compensation for participation or continuation of experimental interventions if they withdraw from the study must also be fully described (see Standard 8.06, Offering Inducements for Research Participation). In specifying compensation, psychologists must include a description of all reasonably anticipated costs. When appropriate, psychologists should consult with university or health care organization administrators regarding the extent to which the institution is responsible for injuries that may result from research participation or whether the investigator’s funding, the health organization, participant, or participant’s health insurer is responsible for coverage of research-related medical care. This information must be included in the informed consent.

**Tribal and International Research and the Role of Others in the Consent Process**

When conducting research involving American Indian and Alaskan Native communities or indigenous villages in countries outside the United States, cultural traditions sometimes require investigators to obtain permission from a tribal leader or village council before they can approach individual community members (Mohatt & Thomas, 2006; National Bioethics Advisory Committee, 2001; Noe et al., 2006). In other cultures, an investigator may be required to obtain permission from a woman’s husband, father, or other male relative before she can be approached for research participation. Obtaining tribal leaders’ or a family member’s permission to recruit individuals for research participation should not be confused with or compromise individual consent. Investigators gaining community permission should approach each individual member and implement consent procedures to ensure that agreement to participate is informed, rational, and voluntary. Substitutive consent should not be conducted in communities where the political structure or power imbalances based on gender compromise the voluntary requirement of consent by placing pressure on individuals to participate where APA Ethics Code Standard 3.08, Exploitative Relationships, may apply (Fisher, 2012). In settings in which respecting individual autonomy may place potential participants in physical danger of spousal or other types of abuse, psychologists need to consider the tension between respect for persons and our duty to do no harm. (More information on research involving vulnerable populations can be found in Chapter 17 of this volume.)

**Informed Consent to Research Involving Children and Adolescents**

In both law and ethics, children have been presumed to lack certain requirements of consent capacity because of immature cognitive skills, inadequate experiences in situations analogous to the research context, and the actual and perceived power differential between children and adults, and such limitations have drawn empirical support for children and early adolescents (IOM, 2004). Ethics
Code Standard 3.10(b), Informed Consent, and federal regulation 45 C.F.R. § 46.408b (DHHS, 2005) require guardian permission for research involving children to provide added protections for populations vulnerable to rights violations.

**Child assent.** Out of respect for children as developing persons, federal regulations (DHHS, 2005, 45 C.F.R. § 46.408a) and the Ethics Code Standard 3.10(b) require investigators to obtain the assent of child participants in a language appropriate to their developmental level. Neither federal regulations nor the Ethics Code, however, stipulates a specific age at which assent must be sought. For each research protocol, investigators and their IRBs must make that determination by taking into account the nature of the research and age, maturity, psychological state, and preferences and history of family decision making of the minor involved (Fisher & Masty, 2006; Masty & Fisher, 2008). According to federal guidelines (DHHS, 2005, 45 C.F.R. § 46.408a) for a specific research project, the assent determination can be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. Moreover, if the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research.

**Exceptions to guardian permission.** Exceptions to the requirement for guardian permission as outlined in 45 C.F.R. § 46.402a (DHHS, 2005) include “emancipated minors” who have assumed adult responsibilities such as self-support, marriage, or procreation, or “mature minors” who according to state law may be treated as an adult for certain purposes (e.g., treatment for venereal disease, drug abuse, emotional disorders). Compounding such decisions is the fact that state laws often are silent on how mature minor laws, designed to permit adolescent receipt of medical and mental health treatment in the absence of guardian permission, apply to research (IOM, 2004). This is one reason why most IRBs do not frequently assert their right to waive guardian permission. Unfortunately, reluctance to waive parental permission often means that life-threatening social conditions of adolescence are not studied (Fisher & Goodman, 2009).

When the research involves no more than minimal risk to participants, guardian permission also may be waived by an IRB if the research will not adversely affect participant rights and welfare, could not practically be carried out without the waiver, and participants provided with additional pertinent information after participation (DHHS, 2005, 45 C.F.R. § 46.116.d; see also Standard 8.08, Debriefing). Research psychologists need to be aware, however, that under federal regulations passive consent procedures (sending guardians forms asking for a response only if they do not wish their child to participate in the research) are not an ethical substitute for guardian permission. Psychologists who do not obtain the active affirmative permission of guardians violate this standard except when the research meets the conditions for Ethics Code Standard 8.05, Dispensing With Informed Consent for Research, or when an IRB waives the requirement for guardian under federal regulations 45 C.F.R. § 46.116d and § 46.408c (DHHS, 2005). The APA and regulatory restrictions on passive consent reflect ethical principle of respect. It reflects society’s obligation to ensure that children are provided the adult supports necessary to make informed and noncoerced consent decisions and recognizes that consent is an intentional act that cannot be assumed by its absence. Research psychologists conducting longitudinal studies with minors also should consider reconsent procedures appropriate to children’s changing consent maturity.

Under 45 C.F.R. § 46.408c (DHHS, 2005), an IRB also may waive guardian permission when there is serious doubt as to whether the parents’ interests adequately reflect the teenager’s interests (e.g., research on child abuse or neglect, genetic testing of the healthy sibling of a child with a mental disorder) or when parental consent cannot reasonably be obtained (e.g., research on runaway youth). Requests to IRBs to waive guardian permission should thus include when relevant (a) state
laws on emancipated and mature minor status; (b) justification of minimal risk status of research; (c) why guardian consent will not be in the child’s best interest or is unavailable; and (d) how an independent participant advocate will be appointed, verify youths’ understanding of procedures, support their participation preferences, and assess reactions to planned procedures (Fisher, Hoagwood, et al., 1996).

Goodness-of-Fit Ethics for Informed Consent to Pediatric Intervention Research

Fisher (2003a, 2003b) has called for an ethics framework for pediatric intervention research that conceptualizes participant respect and protections in terms of the goodness of fit among (a) the child’s developmental capacities and disorder-based vulnerabilities, (b) the parents’ understanding of their child’s health condition and research terminology, (c) the family’s preferred mode of health decision-making for the child, and (d) the unique characteristics of the specific research context. Goodness-of-fit ethics conceptualizes research risks and benefits as a product of both experimental design and child-and-family attributes. Additionally, it shifts judgments regarding ethical procedures away from an exclusive focus on assumed child or parental consent vulnerabilities to an examination of those aspects of the research setting that are creating or exacerbating research vulnerability.

The goodness-of-fit framework calls for scientists to construct informed consent procedures guided by (a) the moral principles of respect, care, and justice; (b) a responsiveness to the abilities, values, and concerns of pediatric research participants and their parents; and (c) an awareness of the scientists’ own competencies and obligations (Fisher, 1997, 1999). These considerations in turn obligate investigators to consider how the consent setting can be modified to produce a process that best reflects and protects the participant’s rights, concerns, and welfare (Fisher, 2003a, 2005). Following a colearning process in which they elicited patient and parent attitudes toward the role of parental permission and adolescent assent in pediatric cancer trials, Masty and Fisher (2008) proposed four factors essential to consider when creating a family-fitted consent process:

- the child’s current cognitive assent capacity and emotional readiness to make clinical research participation decisions,
- parent characteristics that might affect parents’ responsivity to consent information,
- the child’s autonomy strivings balanced with parents’ duty and responsibility to make decisions in their child’s best interest, and
- the family’s history of shared decision making.

INFORMED CONSENT FOR RESEARCH INVOLVING ADULTS WITH IMPAIRED CONSENT CAPACITY

The ethical value of informed consent rests on the assumption that prospective participants are able to understand the nature and rationale of the study as well as their research rights, including the right to freely volunteer and withdraw participation, to receive and understand information about the study, and to have their responses remain confidential. The process of obtaining informed consent presents unique ethical challenges for research involving adults with schizophrenia, mental retardation, Alzheimer’s disease, and other disorders characterized by fluctuating, declining, or long-term impairments in decisional capacity. Obtaining informed consent from these populations raises a fundamental ethical question: How can psychologists balance their ethical obligation to respect the dignity and autonomy of persons with mental disorders to make their own decisions with the obligation to ensure that ill-informed or incompetent choices do not jeopardize their welfare or leave them open to exploitation (Cea & Fisher, 2003; Fisher, 1999; Fisher, Cea, Davidson, & Fried, 2006)?

Legal Status, Diagnostic Labels, and Consent Capacity

The moral claims on science of adults with cognitive impairments should not differ from those who do not have identified mental vulnerabilities. All persons have the right to assume that researchers are obligated to communicate with them honestly, to
respect their autonomy rights and protect their privacy, to design research procedures that minimize harms and maximize benefits, and to treat them fairly (Fisher, 1999, 2003a).

Some adults with serious mental disorders have been declared legally incompetent to consent. Removal of a person’s legal status as a consenting adult does not, however, deprive him or her of the moral right to be involved in treatment or research participation decisions. For these adults, federal regulation 45 C.F.R. § 46.111(a)(4) (DHHS, 2005) and APA Ethics Code Standard 3.10(b) require that psychologists obtain the appropriate permission from a legally authorized person and provide an appropriate explanation to the prospective client–patient or research participant, consider such person’s preferences and best interests, and seek the individual’s assent.

The implementation of ethically appropriate consent procedures is more complex for the many situations in which individuals diagnosed with neurological or other mental health disorders retain the legal status of a consenting adult, although their capacity for making informed, rational, and voluntary decisions may be compromised. Each person with a serious mental disorder is unique. Sole reliance on a diagnostic label to determine a client’s or patient’s capacity to make treatment or research participation decisions risks depriving persons with mental disorders of equal opportunities for autonomous choice. However, although federal regulations call for investigators to provide additional safeguards for mentally disabled persons and others vulnerable to coercion (DHHS, 2005, 45 C.F.R. § 46.111b), the regulations and the Ethics Code do not provide specific guidance on such safeguards. However, the National Institutes of Health (NIH) has developed an interim list of points to consider (NIH, Office of Extramural Research, 2009).

**Fitting Consent Procedures to Enhance Decisional Capacities and Protections**

Grisso and Appelbaum have developed the most well-known model of consent capacity (Appelbaum & Grisso, 2001; Grisso & Appelbaum, 1998). It consists of four increasingly complex consent components: choice, understanding, appreciation, and reasoning. This model has given rise to several empirically validated instruments (Dunn et al., 2007). Assessing capacity is a necessary, but insufficient, basis for determining consent procedures for individuals with mental disorders. Fisher (2012) has provided the following guidance for research psychologists to draw on the Grisso and Appelbaum (1998) psycholegal model to maximize the ethical fit between participant and the research context.

**Choice.** Evidencing a choice reflects the ability to actively indicate consent or dissent. For example, some adults suffering from catatonia or Parkinson’s dementia may be unable to verbally or nonverbally communicate a choice. Although these individuals may understand some of the consent information presented and may have a participation preference, their inability to communicate agreement or dissent will require stringent safeguards against harmful or exploitative consent procedures.

In such settings, creating a goodness of fit between person and consent context often requires respectful inclusion of a consent surrogate who has familiarity with the patient’s preference history. The proxy can help ensure that the consent decision reflects to the extent feasible the patient’s attitudes, hopes, and concerns. Once proxy consent has been obtained, respect for personhood and protection of individual welfare requires psychologists to be alert to the patient’s appropriate expressions of anxiety, fatigue, or distress that indicate an individual’s dissent or desire to withdraw from participation.

**Understanding.** Understanding reflects comprehension of factual information about the nature, risks, and benefits of treatment or research. When understanding is hampered by problems of attention or retention, psychologists can incorporate consent enhancement techniques into their procedures, such as incorporating pictorial representations of research procedures, presenting information in brief segments, or using repetition. Person-consent context fit also requires identifying which information is and is not critical to helping an individual make an informed choice. For example, when seeking consent for a behavioral intervention study addressing aggressive disorders in a residence for adults with developmental disabilities, it may be important for
prospective participants to understand the specific types of behaviors targeted (e.g., hitting other residents), the reward system that will be used (e.g., points toward going to movies or other special activities), and who will be responsible for monitoring the behavior (e.g., researchers or residential staff). It also is important for them to understand the ethical protections (confidentiality) and their research rights (the voluntary nature of participation), although requiring them to be able to articulate details of these procedures may undermine the principle of respect. For example, in a study on the consent capacity of adults with developmental disabilities, Fisher et al. (2006) found that in response to a hypothetical consent protocol, participants clearly understood the concept of confidentiality, often describing it in terms of keeping their records safely “locked in a drawer,” even though the consent information noted only that all information would be kept private and the investigator would tell no one about what the participant had said.

**Appreciation.** Appreciation refers to the capacity to comprehend the personal consequences of consenting or dissenting to research. For example, an individual suffering from schizophrenia may understand that clinical research is testing treatment effectiveness, but may not appreciate she has a disorder that requires treatment. A sliding-scale approach based on the seriousness of personal consequences of the consent decision can be helpful in evaluating the ethical weight that should be given to the participant’s capacity for appreciation. For example, understanding may be sufficient for consent decisions to standard or experimental interventions that present minimal risk and are supplemental to current treatment programs. On the other hand, appreciation may be essential when experimental interventions may expose the individual to the risk of serious side effects or offer an opportunity to receive needed services otherwise not available.

**Reasoning.** Reasoning reflects the ability to weigh the risks and benefits of consent or dissent. An individual’s right to independently consent to experimental treatment sometimes is judged in terms of his or her ability to not only understand the nature of the experiment, but also to rationally calculate whether the possibility of deriving benefit from the research out weighs the risks. Holding persons to this standard of cognitive competence often has justified widespread substitute decision making for those with mental impairments, especially when the disabled person refuses participation based on disagreement with the risk-benefit assessment of the IRB, investigators, and caretakers. As beneficent as such an approach may appear, Fisher has argued that such judgments may unintentionally violate the principle of justice (Fisher, 1999, 2002a, 2002b, 2003b). For example, who decides what is or is not a rational criterion for a risk-benefit calculation? Should such a criterion be used to take away the rights of persons to decide whether they wish to decline participation in social behavioral experimentation when the equally nonrational preferences to decline research participation made by adults without diagnosed impairments are not questioned?

For example, an adult with schizophrenia with paranoid features may understand the nature of an experimental treatment and appreciate its potential for reducing his anxiety, but the person may reason that the risks outweigh the potential benefits because the psychologist offering the treatment is part of a conspiracy to undermine his freedom. Similarly, an adult with midstage Alzheimer’s disease may understand the minimal risks posed by the experimental procedures in a nontreatment study using the Tower of Hanoi (Welsh & Huizinga, 2001) to test planning ability, but the person may judge as a serious risk the possibility of inflicted insight caused by personal failure on these tasks—and in many cases may not be able to articulate his or her reasoning to investigators. Adults without an identified disorder also may reject participation because they do not trust the intent of investigator or have a heightened fear of failure, but their participation refusal will not be questioned. Defining consent competency in terms of whether participants attribute the same weight to research risks and benefits as their nonimpaired peers in some circumstances does not do justice to significance of emotions, needs, and practical experiences that contribute to human judgments.

**Consent and empowerment.** People with long-standing, declining, or transient disorders related
to decisional capacities may be accustomed to other people making decisions for them and may not understand or have experience applying the concept of autonomy. In institutional contexts, individuals with mental disorders may fear disapproval from doctors or residence supervisors or feel they must be compliant in deference to the authority of the requesting research psychologist. Some may have little experience in exercising their rights, or if they are living in a community residence, may be fearful of discontinuation of other services. Psychologists also can look toward recent research demonstrating the effectiveness of brief interventions to enhance consent capacity in adult patients (Mittal et al., 2007). Modifying the consent setting to reduce the perception of power inequities, providing opportunities to practice decision making, demonstrating that other services will not be compromised, and drawing on the support of trusted family and peers can strengthen the goodness of fit between person and consent setting and ensure that informed consent is obtained within a context of justice and care.

To facilitate IRB review of protocols involving participation of adults with questionable consent capacity, psychologists may facilitate the review by providing evidence that their consent procedures are (a) sensitive to differing and fluctuating levels of capacity, (b) tailored to the specific research context, (c) timed to avoid periods of heightened vulnerability, and (d) repeated when studies are longitudinal. IRB applications also should include legal, psychological, and ethical criteria for determining consent capacity and decisions regarding when and from whom surrogate consent will be sought and how the voluntary nature of participant assent will be obtained and protected (see Appelbaum, Grisso, Frank, O'Donnell, & Kupfer, 1999; Carpenter et al., 2000; Fisher, 2002a; also see APA, 2010a, Standard 3.10(b), Informed Consent).

DISPENSING WITH INFORMED CONSENT FOR RESEARCH

According to both federal regulations (DHHS, 2005, 45 C.F.R. § 46.116(c–d)) and the Ethics Code (Standard 8.05, Dispensing With Informed Consent for Research), an IRB may approve and an investigator may request a consent procedure that does not include, or alters, some or all of the elements of informed consent or waives the requirement to obtain informed consent. Under federal regulations such conditions include (a) government-approved research on public programs and (b) minimal risk research that could not practically be carried out without the waiver or alteration, but that does not adversely affect the rights and welfare of participants and, whenever appropriate, provides participants additional pertinent information after participation.

Ethics Code Standard 8.05 restricts dispensing with informed consent for research to three well-defined conditions—all of which are predicated on the condition that the research will not create distress or harm. Drawing on Fisher (2012), these conditions are described in the following sections.

Research Conducted in Schools

Ethical justification for waiving the informed consent requirement for specific types of research conducted in education settings is predicated on the right and responsibility of education institutions to evaluate their own programs, practices, and policies to improve services as long as the research procedures do not create distress or harm. Studies of normal education practices that do not require informed consent include comparisons of different instructional methods and classroom management techniques, or evaluation of education placements.

In elementary and secondary school settings, dispensing with informed consent is a waiver of guardian permission for research involving persons who are legally incapable of consent. Irrespective of whether the type of research conducted meets the criteria for waiving parental permission under this standard, psychologists should consider state and federal laws and parental expectations regarding parental involvement in children’s participation in normal educational practices before deciding whether to dispense with parental permission or student assent. Psychologists conducting program evaluation in the schools also should be familiar with the Family Educational Rights and Privacy Act of 1974 and other federal regulations that may require parental access to their child’s school.
records regardless of whether parental permission for the evaluation was required or obtained.

Permission to dispense with informed consent for research in education settings does not apply to studies designed to describe or test hypotheses regarding the relationship between student personality traits or mental health disorders and school performance (e.g., gender differences in math anxiety and its relationship to scores on a math achievement test). The assessment of such personal characteristics is not a part of normal educational practice and could constitute an invasion of privacy. In addition, some investigator-initiated school-based programs, such as drug prevention programs, may not be considered a normal educational practice or part of the school curricula and thus would not meet the Standard 8.05 criteria for waiver of parental permission or child–adolescent assent or consent. Investigators conducting such studies must either follow the consent requirements outlined in 45 C.F.R. § 46.116 and § 46.408 (DHHS, 2005) and Ethics Code Standard 3.10, Informed Consent, and Standard 8.02a, Informed Consent to Research, or obtain a waiver of parental permission from their IRB in compliance with these regulations and standards.

Anonymous, Naturalistic, or Archival Research

Informed consent is not required for investigations using anonymous questionnaires, naturalistic observations, or archival research when (a) confidentiality is protected; (b) disclosure of responses would not place participants at legal, financial, or social risk; and (c) the research methods would not reasonably be expected to cause distress or harm. The phrase “for which disclosure of responses would not place participants at risk” (APA, 2010a, Ethical Standard 8.05) refers to both the certitude that participants could never be identified and the nature of data collected. Thus, unless anonymity can be assured, psychologists should avoid dispensing with informed consent when personal information collected would create participant distress or involve criminal activity, substance abuse, or other activities that if known would place the participant at risk.

When research is conducted through the mail or on the Internet and adequate protections are put in place to ensure that participants’ responses are anonymous (e.g., postmarks will not reveal participants’ home addresses, web-based responses cannot be linked to identifying information), informed consent information must be provided at the beginning of the survey, in the same detail required by Standard 3.10, Informed Consent, and Standard 8.02, Informed Consent to Research. However, documentation of consent (e.g., name and signature confirming agreement) is not required because (a) completing the survey and mailing it to the investigator or submitting it via the Internet is considered evidence of voluntary consent, and (b) requiring identifying documentation would compromise participant anonymity.

Studies of individual responses in chat rooms and on listservs may be considered naturalistic observation if the users have no reasonable expectation of privacy and the investigator is not manipulating the discussion to test or elicit particular responses. Under Standard 8.05, psychologists may dispense with informed consent under these situations if protections are in place to guard against personal identification and harm. Investigators should also consider whether the uniqueness of the population studied (e.g., individuals from small and geographically restricted ethnocultural communities; persons with rare genetic, medical, or psychological disorders) increases the probability that anonymous, naturalistic, or archival procedures may not be sufficient to safeguard identification of participants or their immediate community (Fisher et al., 2002).

Studies of Job or Organization Effectiveness

Subpart 1(c) of Ethics Code Standard 8.05 recognizes the right and responsibility of organizations to draw on the research expertise of psychologists to investigate factors related to job or organization effectiveness as long as (a) research participation does not pose a direct risk to an individual’s current employment status, (b) confidentiality is adequately protected, and (c) the research procedures would not be expected to create distress or harm. This standard is meant to apply to dispensing with informed consent to research directly linked to a specific organization’s needs and not to studies
designed to test general hypotheses regarding organizational effectiveness.

The phrase “not reasonably be assumed to create distress or harm” highlights the fact that in most circumstances it would be ethically inappropriate to dispense with informed consent for organizational effectiveness studies using measures of psychopathology or biological data because assessment of mental health or physiological responses without consent can violate an individual’s right to privacy of information not directly related to job performance and can be experienced as personally intrusive and distressful (see Fisher, 2012, for detailed examples of the meaning of qualifying terms, such as meaningful, throughout the Ethics Code).

Waiving Consent for Recording Voices and Images in Research

Under Ethics Code Standard 8.03, investigators may record the voices and images of persons without their consent if (a) observations occur in a public setting in which one would have no reasonable expectation of privacy, for example, a public park, a hotel lobby, a street corner; (b) procedures do not disturb or manipulate the natural surroundings; and (c) protections are in place to guard against personal identification and harm, especially when the behaviors observed place participants at legal or social risk, for example, vandalism. Investigators conducting deception research that meets the requirements of Standard 8.07, Deception in Research, can receive approval from their IRB to waive the requirement to obtain consent for recording before data collection, but they must seek permission to use recordings for data analysis from participants during debriefing. Recordings must be destroyed if the participant declines permission.

MAINTAINING CONFIDENTIALITY

Psychologists respect the privacy and dignity of persons by protecting confidential information obtained from those with whom they work (Principle E, Respect for People’s Rights and Dignity). Standard 4.01, Maintaining Confidentiality (APA, 2010a) is broadly written and requires all psychologists to take reasonable precautions to maintain confidentiality.

Federal regulation 45 C.F.R. § 46.111(a)(7) (DHHS, 2005) is similarly broad. The nature of precautions required will differ according to the nature of the data to be collected; the age, competency, and legal status of the participant and relevant federal regulations; state and local laws; and institutional and organizational policies. The term reasonable precautions (APA, 2010a, Standard 4.01) recognizes both the responsibility to be familiar with appropriate methods of protecting confidentiality and the possibility that confidentiality may be broken despite an investigator’s best efforts.

Common Strategies for Maintaining Confidentiality

Strategies for protecting participant confidentiality include using participant codes on all data collection materials and data entered for analysis, maintaining records linking participant codes to personal identifiers in a secure file and destroying such records once they are no longer needed, limiting access to personally identifiable information, supervising research personnel in routine confidentiality precautions, and separating consent forms from coded materials to avoid participant identification.

Research involving small or unique populations.

When publishing or otherwise disseminating research findings, it is important to consider special confidentiality protections when unnamed, but small, unique samples can be identified through descriptions of demographic variables (e.g., persons with rare diseases from distinct communities). Similarly, investigators should work to ensure that recruitment and research procedures do not inadvertently reveal confidential information. For example, when studying addictions, mental disorders, sexually transmitted diseases, or other potentially stigmatizing conditions, approaching target populations for recruitment may result in public identification of individuals who have the condition (Fisher, 2004a).

In international behavioral science research, the investigator and participant community may differ in their concepts of physical, informational, and decisional privacy (Goldman & Choy, 2001). In some communities with less rigid building structures and cultural values emphasizing community
openness and family interdependence, participants may question the motives of an investigator who attempts to protect privacy by conducting research interviews in a secluded area and in the absence of family members (Monshi & Ziegelmayer, 2004). In cross-cultural research, therefore, it is important to determine how the participant population defines and values privacy, to design confidentiality procedures to reflect these values, and to clarify during informed consent how confidentiality safeguards have been selected to respect community values and fulfill investigators' ethical responsibilities (Fisher, 2012).

**Use of the Internet and other electronic media.** According to Fisher (2012), Ethics Code requirements for collecting research data over the Internet obligates psychologists to become knowledgeable about or obtain technical assistance in employing appropriate methods for protecting confidential records generated or obtained by the investigator, including encrypted data, password protections, and firewall techniques. When files are stored via a common server or backed up on a university system or hub server, investigators are wise to discuss and develop security measures with appropriate personnel. When scientists electronically transmit confidential information via e-mail, facsimile, or electronic media to other scientists or professionals, they should take reasonable steps to ensure that recipients of the information have an adequate confidentiality policy. (More information on this subject can be found in Chapter 18 of this volume.)

**Confidentiality risks during recruitment.** In field settings such as public parks in which recruitment of participants for research on violent or illegal behaviors often takes place, investigators frequently find that routine procedures for ensuring confidentiality (e.g., participant codes, secure storage and limited access, disposal of unnecessary information, supervision of research personnel, and anonymous data collection) do not provide sufficient protections. For instance, confidentiality risks arise when investigators known by the community to be studying drug use or gang membership approach prospective participants for research recruitment. The recruitment activity can arouse the suspicion of police or other community members to the nature of the participants' behaviors. In some cases, the contact may lead to arrest or physical jeopardy if other drug users or gang members believe the participant is revealing information that may lead to their arrest. Similar concerns arise if studies involving domestic violence, child abuse, or HIV risk require prospective participants to go to a testing site that is easily identified by other community members, or when interviews are conducted in the community for ethnographic research (Fisher, 2004a; Fisher & Goodman, 2009). To avoid recruitment procedures that risk violating participant privacy and welfare, before recruitment, psychologists may wish to consult with prospective participants, community members, police, and others to increase confidentiality and privacy protections in these situations.

**The Certificate of Confidentiality**
The Public Health Service Act (1944–2006) permits investigators to apply for a Certificate of Confidentiality issued by the NIH and other DHHS agencies. The certificate protects investigators from being forced or compelled by law enforcement or subpoena to disclose personally identifiable research information that could place participants in legal jeopardy or damage their financial standing, employability, insurability, or reputation. The certificate does not protect investigators from being compelled by law to release confidential information related to suspected child abuse and it does not preclude investigators from voluntarily disclosing confidential information. If investigators who have acquired a certificate intend to make certain voluntary disclosures to protect the research participant or others from harm (see Standard 4.05, Disclosures), the consent form should detail both the certificate protections and the limits of confidentiality (Fisher et al., 2002; Fisher & Goodman, 2009).

**Data Storage and Disposal**
Ethics Code Standard 6.02, Maintenance, Dissemination, and Disposal of Confidential Records of Professional and Scientific Work, requires that psychologists protect the confidentiality of scientific information in all phases of record creation, maintenance, dissemination, and disposal. The standard
refers to confidential records or data in the form of written and printed materials, automated scoring reports, audio and video recordings, Internet websites or e-mails, company computer networks, storage on hard drives or disks, and facsimiles. Steps that can be taken to protect confidentiality include (a) keeping records in a secure place, (b) limiting access to staff or team members who must use the record to competency perform their duties, (c) de-identifying records using code numbers or other methods, or (d) disposing of tapes and other identifiable records when they are no longer needed and their disposal is consistent with law.

Psychologists should be careful not to assume that their research staff or employees of an institution or company with which they work are familiar with confidentiality requirements or appropriate confidentiality procedures. To the extent it is under their control, they must take steps to ensure that confidential records are kept secure from staff members who do not have approved access.

Disclosures

Social–behavioral research frequently is designed to elicit sensitive information about personal problems and illegal behaviors to generate critical knowledge about the correlates, sequelae, and personal and social mediaters of individual, group, and societal problems. Such information can include studies of health-compromising behaviors, such as alcohol and drug use, high-risk sexual behavior, and suicide, as well as potentially criminal activities associated with violence, child abuse, or purchasing and selling of illegal drugs. Obtaining such information raises unique confidentiality and disclosure concerns. On the one hand, disclosure of such information could place participants or their family members in social, physical, economic, or legal jeopardy. On the other hand, such research often reveals information about serious physical, psychological, or social problems (e.g., suicidality, toxic drug dose administration, sexually transmitted disease) that place the participant in immediate jeopardy or uncover aspects of participants’ behavior that pose a serious threat to known others, such as a planned gang hit, a violence-prone participant obtaining a gun, or identified sexual partners naive about the participant’s highly contagious sexually transmitted diseases.

Federal and Professional Guidelines

Federal guidelines are largely silent on specifying situations for which a disclosure policy for confidential research data should be developed. Ethics Code Standard 4.05(b) provides greater specificity, by describing those situations in which it is ethically permissible to disclose identifiable confidential information without the consent of the participant. This standard is permissive rather than mandatory, however, leaving the decision to disclose confidential information under the listed categories to the psychologist’s discretion. Not surprisingly, research psychologists, especially those conducting nonintervention research with high-risk populations, have been cautious about disclosure policies for information about participants uncovered during research in cases in which (a) using assessments designed to evaluate differences between groups may lack diagnostic validity for individual participants or groups; (b) taking action to help participants (e.g., making referrals for treatment) can threaten the internal validity of a research design (especially longitudinal designs); (c) disclosing confidential information may create participant mistrust or jeopardize recruitment; (d) disclosing information runs the risk of creating harmful or stressful consequences for participants or risk disclosures that inappropriately overestimate mental health problems among minority participants (Fisher, 1994, 1999; Fisher & Goodman, 2009; Fisher, Higgins-D’Allesandro, Rau, Kuther, & Belanger, 1996; Scott-Jones, 1994).

Mandated Reporting

Ethics Code Standard 4.05 permits disclosures mandated by law. This can include state laws governing mandated reporting of child abuse, harm to others, and court orders for data. Research psychologists who are not licensed practitioners often are confused regarding their status as child abuse and neglect mandated reporters. States have varying definitions of who within the general citizenry are mandated reporters. Some restrict the reporting laws to health and mental health practitioners and school professionals, others specify researchers in the
reporting law, and others require all citizens within the state to report suspected child abuse. Psychologists conducting research involving populations at risk for revealing information of suspected child abuse should consult their state law to determine whether they are mandated reporters. In addition, if they are conducting research in a school, social service, or health care setting, they should determine the reporting responsibilities of those collaborating on the research and incorporate appropriate disclosure policies into their research procedures and informed consent (Fisher, 2012).

**Harm to Others**

Research psychologists should also remain up-to-date on whether duty-to-protect laws apply to research. Investigators who study violent behavior may learn that a research participant is intending to harm a third party. Duty-to-protect laws typically require certain classes of health care professionals to inform a third party of the prospect of being harmed by a client–patient or take some other action designed to prevent harm. Although there has yet to be case law in the area of research, investigators need to give appropriate consideration to whether their relationship to a research participant meets the duty to protect outlined by *Tarasoff v. Regents of the University of California* (1976), which requires informing a third party of the prospect of being harmed if one has (a) a “special relationship” with the prospective assailant, (b) the ability to predict that violence will occur, and (c) the ability to identify the potential victim. Appelbaum and Rosenbaum (1989), for example, have argued that researchers specializing in violence may be seen as having more expertise than individual health care providers in the ability to predict that an individual will carry through on a violent threat. They also note that the term special relationship is legally ambiguous and may or may not be applied to research psychologists in some experimental contexts. (More information on *Tarasoff* as it relates to psychological treatment can be found in Volume 1, Chapter 14, this handbook.)

In developing confidentiality and disclosure policies for research involving high-risk behaviors, investigators may benefit from preliminary discussions with members of the prospective participant population to learn their views. For example, Fisher, Oransky, et al. (2009) found that in focus group discussions, many active street drug users were in favor of an ethnographic researcher disclosing information on a participant’s HIV status to the participant’s partner if (a) participants told the investigator they chose to knowingly keep their HIV positive status from their partner; (b) the partner was HIV negative, identified by the participant, and also a participant in the study; and (c) the possibility that confidential information would be disclosed to protect a third party from harm was included in the original informed consent.

**Suicidal Intent**

Under Standard 4.05(b) psychologists are permitted to disclose confidential information to protect individuals from self-harm. It is difficult to determine when it may be ethically appropriate for investigators to take steps to protect a participant from self-harming behaviors. Although clinical interviews and assessments used to determine suicide risk severity are available, they have not been shown to reliably predict the imminence of such a risk on the behavior of a specific individual. In mental health treatment research for depression and other disorders known to be associated with suicidal risk, for which comprehensive psychological assessment batteries are administered, clinical investigators—as part of the data safety monitoring and risk minimization procedures—need to develop empirically informed objective criteria. All members of the research team will use these criteria to determine when a participant’s responses require action and what those actions should be (e.g., immediate intervention, referral to clinician, informing relatives of risk, elimination from the study; Fisher & Goodman, 2009). The ethical choices are similar for investigators conducting nonintervention research with the following caveats: (a) determine whether the measures or items suggesting suicidal ideation are valid indicators of an individual’s mental health status, (b) recognize the limitations of their competence if they are not trained clinicians and recognize the risk of creating a dual relationship with participants if they do have clinically training, (c) identify
appropriate referrals, and (d) include disclosure information in informed consent (Fisher, Higgins-D’Allesandro, et al., 1996).

Investigators utilizing surveys to better understand suicidality also can enhance identification of experimentally induced risk by empirically examining survey or interview participants’ postexperimental reactions (Gould et al., 2005) or by debriefing participants to address any distress evoked. Drawing on participant perspectives can inform development of appropriate disclosure policies. For example, in a series of studies examining the perspectives of adolescents and parents about the ethics of adolescent risk research, Fisher and her colleagues repeatedly have found that the majority would desire referrals for assistance if suicidal ideation was uncovered, and many would want parents or counselors to be contacted (Fisher, 2002c, 2003b; Fisher, Higgins-D’Allesandro, et al., 1996; O’Sullivan & Fisher, 1997).

Steps for Determining Confidentiality and Disclosure Procedures
Ethical decisions regarding confidentiality and disclosure procedures are not singular or static. Every research project requires a series of decision points that build to the construction of best ethical practices for the particular population and research context. Fisher and Goodman (2009) provided a multistep decision-making strategy for constructing responsible confidentiality and disclosure policies for high-risk research. Drawing on Fisher’s goodness-of-fit framework, the strategy assumes that the nature and probability of disclosure challenges are a product of both participant risk characteristics and the type of information the research will elicit. It also assumes that researchers have the expertise to anticipate disclosure challenges on the basis of their familiarity with extant literature and in many cases previous research experience with similar populations. To reach the best fitted confidentiality and disclosure policy for a specific research design Fisher and her colleagues (Fisher, 2012; Fisher & Goodman, 2009; Fisher, Higgins-D’Allesandro, et al., 1996) suggested the following:

- Whenever possible, ethical challenges involving the potential need to disclose confidential information specific to the research design and participant population should be anticipated.
- To avoid overidentification of risks that may require disclosure, determine whether the nature of the data collected is a valid indicator of individual risk and relatedly whether the research team has the competence to assess the risk.
- Determine whether there are relevant reporting laws that need to be considered and investigate whether there are available institutional or community services that could be called on as referral sources.
- If indicated by the noted steps, before initiation of the study develop and train the research team in specific criteria for confirming risk and steps to take if these criteria are met.
- Whenever possible, draw on the perspectives of prospective research participants or community advisory boards in developing fair and effective policies—an essential element of fair and effective disclosure policies.
- Inform prospective participants about the disclosure policy during informed consent in the detail needed to make an informed decision.
- Monitor the policy, invite feedback from participants and staff, and modify the process if necessary; inform the IRB of any proposed changes.

RESEARCH REQUIREMENTS IN HIPAA
Informed consent and confidentiality policies for psychologists conducting research involving participant health information need to be familiar with requirements of HIPAA (1996). As will be discussed, psychological scientists who create, use, or disseminate data that meet the HIPAA definition of protected health information (PHI) will need to incorporate relevant HIPAA requirements in developing and administering informed consent and confidentiality procedures. This includes psychologists who create, use, or disclose PHI during the conduct of research evaluating health interventions, such as different therapeutic techniques; data produced from nonintervention research, which nonetheless will be included in a participant’s health records; archival research on PHI collected by an institution; or any research is conducted in an organized system.
of health care (HIPAA, 1996). A brief overview of the regulations and relevant terminology for research is provided in the following sections. (More information on the implications of HIPAA for psychological research and practice can be found in Fisher, 2012.)

To What Does HIPAA Apply?
HIPAA regulations apply to PHI, which is defined as oral, written, typed, or electronic individually identifiable information related to (a) a person’s past, present, or future physical or mental health; (b) provision of health care to the person; or (c) past, present, or future payment for health care. For health information to come under the definition of PHI, it must be created by an employer or by the following covered entities: a health plan, a health care clearinghouse, or a health care provider who transmits any health information in electronic form in connection with financial or administrative activities related to health care. Psychologists also need to be familiar with state laws relevant to patient–participant privacy because under the regulation, state laws preempt HIPAA when they are more protective from the standpoint of the patient.

What Do Covered Entities Need To Do to Comply With HIPAA?
It is important for researchers, who themselves are not covered entities, to understand the obligations of institutions where research may be conducted or from whom patient records will be requested as part of the study. Under HIPAA, covered entities must (a) provide information to patients about their privacy rights and the covered entity’s privacy practices, called a notice of privacy practices; (b) permit patient access to records and upon patient request provide an accounting of disclosures of PHI made to others over the past 6 years; (c) obtain patient authorization for use and disclosures to others in a manner and for purposes specified in the regulations; (d) implement clear privacy procedures for electronic transmission and storage of PHI; (e) designate a privacy officer; (f) implement security procedures that prevent unauthorized access to health records; (g) train and ensure that employees comply with privacy, transaction, and security procedures; (h) reasonably ensure that business associates, individual contractors, consultants, collection agencies, third-party payers, and researchers with whom PHI is shared comply with privacy and transaction rules; and (i) attempt to correct violations by these other entities if they occur or cease the relationship.

Which HIPAA Rules Apply Specifically to Researchers?
HIPAA defines research as “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge” (HIPAA, 1996, 45 C.F.R. § 164.501). Treatment is defined as

Pschologists who are health care providers or who employ health care providers to conduct research involving assessments or diagnoses that will be used for treatment decisions involving research participants should consider themselves or their research team covered entities under HIPAA. Investigators who are not health care providers but conduct treatment research or quality improvement research for a health care facility or any other organization that is a covered entity also must ensure that their procedures are HIPAA compliant.

Most researchers or members of their team who create, use, or disclose PHI as part of a randomized clinical trial or other forms of health-relevant intervention research will be considered covered entities. Researchers who are not involved in intervention research but who plan to use in their research data coming under the definition of PHI created by a
covered entity must provide to the covered entity written assurance that they will comply with HIPAA standards. HIPAA permits covered entities to transmit PHI to researchers who are conducting nontherapeutic research if (a) a patient signs an authorization to release information that is project specific (not a general authorization for use of PHI for future unspecified research); (b) an IRB or HIPAA-defined privacy board approves in writing a waiver of the requirement for such authorization and the investigator provides the covered entity with written assurances that HIPAA-compliant procedures are in place to protect confidentiality; or (c) the records are deidentified, as specifically defined by HIPAA regulations.

Authorization to Use PHI for Research
For a covered entity to create, use, or disclose PHI for research purposes, HIPAA requires the covered entity to receive a signed authorization from the prospective participant or a legal guardian limited to the specific research project (45 164.508(c)). Research is one of the few activities for which HIPAA permits authorization for the use or disclosure of PHI to be combined with informed consent information and other types of written permission for the same research (HIPAA, 1996, 45 C.F.R. § 164.508(b)(3)(i)). Although there is overlap between HIPAA authorization language and traditional informed consent requirements, investigators should be aware that under HIPAA, a valid authorization must contain (a) specific identification of the person(s) who will be involved in the request for, use, and disclosure of PHI; (b) description of each purpose of the requested use or disclosure; (c) an expiration date for the authorization; and (d) a statement regarding the participant’s right to revoke the authorization in writing. Investigators conducting research with children and adolescents also should become familiar with relevant HIPAA regulations (Fisher, 2004b).

HIPAA also provides specific exception for research from requirements of practice, and these must be explained in the authorization. First, if the PHI already has been obtained and used on the basis of the original authorization, the investigator may maintain data analyses based on that information if a participant exerts a right to revocation, although no additional information may be used or disclosed following revocation. Second, prospective participants must be informed that research is one of the few conditions in which HIPAA permits treatment to be conditioned on authorization (HIPAA, 1996, 45 C.F.R. § 164.508(b)(4)(i)).

Health Records Research
HIPAA is relevant for research psychologists conducting records research on PHI collected by social services agencies, hospitals, or other health or service provider institutions. (The question of when and if social service agency records are or are not to be considered PHI is often agency specific, and psychologists working with these organizations would be wise to explore HIPAA implications at the design stage of research.) With some exceptions, covered entities can allow investigators access to PHI only if the covered entity obtains authorization by the client–patient or a legally authorized representative to release PHI for the specific research purposes and to the specific investigator or investigative team. Whenever a covered entity releases PHI to an investigator, the covered entity is required to disclose only the “minimum necessary” to reasonably achieve the purpose of the disclosure (HIPAA, 1996, 45 C.F.R. § 164.514(3)). This type of protection is consistent with Ethics Code Standard 4.04, Minimizing Intrusions on Privacy.

HIPAA Requirements for Use of PHI for Research Without Patient Authorization
HIPAA does specify conditions under which patient authorization is not required. Under HIPAA, PHI may be used for research purposes without client–patient authorization if the covered entity who is being asked to disclose the PHI receives written documentation that waiver of patient authorization has been approved by an IRB in conformance with federal guidelines, and if (a) the use or disclosure of PHI involves no more than minimal risk to the individuals, (b) the alteration or waiver will not adversely affect patient privacy rights and welfare and privacy risks are reasonable in relation to the anticipated benefits of the research to participants or to scientific knowledge, (c) the research could not practicably be conducted without the alteration or
waiver and without access to the use of PHI, (d) there is an adequate plan to protect the identifiers from improper use and disclosure and to destroy identifiers at the earliest opportunity, and (e) there are adequate written assurances that the PHI will not be reused or disclosed to any other person or entity (Rules for Research are in HIPAA, 1996, 45 C.F.R. § 164.501, § 164.508(f), and § 164.512(i)). Covered entities also may waive the requirement for client–patient authorization for the use and disclosure of their PHI if it is deidentified by the covered entity (HIPAA, 1996, 45 C.F.R. § 164.512(i) and § 164.514), used only for the purpose of preparing a research protocol, or the patient is deceased and information is restricted to a limited data set (as specifically defined by HIPAA, 1996, 45 C.F.R. § 164.513(c)(2)).

Disclosures and HIPAA
Ethics Code Standard 4.05(a), Disclosures, requires psychologists to be mindful of laws that prohibit disclosure. HIPAA requires that covered entities obtain written valid authorization from the individual or his or her personal representative before releasing PHI (HIPAA, 1996, 45 C.F.R. § 164.508). The authorization must include a specific description of information to be disclosed, specific identification of the person or class of persons who can make the authorization and to whom information may be disclosed, a description of the purpose and use of the disclosure, an expiration date, and signature (HIPAA, 1996, 45 C.F.R. § 164.508(c)). In addition, when appropriate release and authorizations are obtained, the HIPAA Privacy Rule requires psychologists share only the minimum amount of information necessary for billing agencies and non-health provider internal staff to perform their roles (HIPAA, 1996, 45 C.F.R. § 164.502(b)).

Declining Participant Requests for Research-Generated PHI
Under Standard 4.05(a), psychologists may decline an appropriately obtained request to release confidential information if the psychologist believes disclosure will cause harm. However, psychologists should be aware that certain federal and statutory laws limit providers’ rights to withhold such information. Under the HIPAA Privacy Rule, covered entities have an obligation to agree to a patient’s reasonable requests for release of PHI and can deny a request only if it is reasonably likely to endanger the life or physical safety of the individual or another person or is likely to cause equally substantial harm. In addition, psychologists must allow clients–patients the right to have the denial reviewed by a designated licensed health care professional. (More information on how decisions regarding disclosure of information relate to Standard 9.04, Release of Test Data, and Standard 9.11, Maintaining Test Security, can be found in Chapter 12 of this volume.) An individual’s access to PHI created or obtained in the course of treatment research may be suspended for as long as the research is in progress, provided the individual has agreed to the denial of access when consenting to the research and has been promised right of access upon completion of the research (HIPAA, 1996, 45 C.F.R. § 164.524(a)(2)(iii)).

DECEPTION IN RESEARCH
Deceptive techniques intentionally withhold information or misinform participants about the purpose of the study, the experimental procedures or equipment, or the roles of research team members (Sieber, 1982). Under APA Ethical Principle C, Integrity, deception should be avoided unless it is necessary to maximize benefits and minimize harms. Deception research may produce benefits unavailable through alternative methods by keeping participants naïve about the purpose and procedures of a study, thereby increasing methodological realism and spontaneous response to experimental manipulation. However, these advantages may not be actualized if participants are predisposed to be suspicious of psychology experiments or are actively engaged in hypotheses regarding an experiment’s true purpose (Fisher & Fyrberg, 1994).

The Consent Paradox
By its very nature, informed consent for participation in a deception study creates a moral paradox by compromising an individual’s ability to make a fully informed decision about research participation (Fisher, 2005). The ethical imperative for informed
consent to research participation arose following the revelation during the Nuremberg trials of Nazi medical science atrocities. The Nuremberg Code (1946) codified the international community’s distrust in scientists’ motivation to make decisions that would serve the best interests of participants, and informed consent of the participant rather than morally responsible decisions by scientists came to be seen as the primary means of protecting participant autonomy and welfare. Informed consent to a deception study reflects the moral ambiguity continuing to surround respect for participant autonomy inherent in professional ethics codes and federal regulations. During the consent process, investigators conducting deception research intentionally give participants false information about the purpose and nature of the study. Individuals providing an affirmative response to participate are erroneously led to believe they have autonomy to decide about the type of experimental procedures they are willing to be exposed to, when in fact they do not and thus have no decisional control over these experiences or the potential discomfort that may arise at the end of the study when they are debriefed about the deception (Fisher, 2005, 2012). For these reasons, deception research is required to meet more stringent criteria for implementation than nondeceptive studies.

Scientific and Social Justification

Federal regulations do not specifically address deception research. IRBs must rely on general criteria for waiving consent requirements (DHHS, 2005, 45 C.F.R. § 46.116(c,d)) and a risk–benefit assessment (DHHS, 2005, 45 C.F.R. § 46.111) to determine whether to approve a protocol using deceptive methods. Ethics Code Standard 8.07, Deception in Research, provides greater specificity. In the first part of the standard, 8.07(a), deception studies are ethically justified only if psychologists demonstrate that (a) prospective benefits to science or society significantly outweigh violating participants’ right to determine whether they want to be involved in the type of experimental procedures for which they are recruited and (b) nondeceptive alternative procedures do not offer sufficient scientific controls to test the hypothesis under investigation. Some alternative methodologies that can be considered include naturalistic observation, field or game simulations, role-playing, or experimental methods. Failure to use scientifically valid nondeceptive alternative methods simply because of inconvenience or financial cost under some circumstances may be a violation of this standard.

Even if deceptive techniques have significant scientific, educational, or social value and thus meet the criteria of Standard 8.07(a), Standard 8.07(b) prohibits withholding or misleading prospective participants about procedures causing physical pain or severe emotional distress. The prohibitions in this standard are absolute and do not depend on the duration of physical pain or whether severe emotional harm can be alleviated during debriefing procedures.

Debriefing

When deception is used, participants must be informed about a study’s deceptive aspects as soon as possible, preferably at the end of their participation. This procedure often is called dehoaxing. In some instances, participants may find revelations about the deception and true purpose of the study to be educative; in other cases, there may be transient or long-term discomfort or distress arising from perceptions of invasion of privacy or loss of self-esteem and negative reactions to being observed or induced to commit what the participant may perceive as embarrassing or reprehensible acts (Baumrind, 1985; Fisher & Fyrberg, 1994).

There may be situations in which explaining the deception can compromise the methodological validity of the research involving future participants, for example, if research is conducted in a small university where students are likely to speak with one another about their experiences. In such circumstances, dehoaxing may be delayed until data collection is completed. Psychologists also must take reasonable steps to alleviate psychological harm resulting from dehoaxing and may withhold information about deceptive procedures to protect the participant from harm. The general responsibility to debrief participants is outlined in Ethics Code Standard 8.08(b) and 8.08(c), Debriefing.

Data Withdrawal

Under Standard 8.07(c), psychologists must permit participants to withdraw their data after learning
about the deception. Although the standard stops short of requiring psychologists to ask participants if they want to withdraw their data, dehoaxing procedures should not preclude participants from making such a request. Giving individuals an opportunity to withdraw data should not be interpreted as implying their deferred consent to the deception—informed consent can only be prospectively obtained (Office for Protection From Research Risks, DHHS, NIH, 1993). (More information on deception research can be found in Chapter 19 of this volume.)

CONFLICTS OF INTEREST IN COMMERCIALLY FUNDED RESEARCH

Advances in training programs in neuropsychology, psychopharmacology, and pharmacotherapy have been accompanied by increased participation of psychologists in research on psychoactive and central nervous system medications, drugs, and chemicals. Growing involvement in the empirical assessment of psychotropic medications is likely to be paralleled by increased funding for research psychologists from pharmaceutical companies. Psychologists who are unfamiliar with private industry sponsorship of research may be unprepared for the ethical challenges that arise.

What Is Conflict of Interest in Research?

Federal regulators and research organizations are consistent in their definitions of conflict of interest in research as instances in which financial considerations may compromise an investigator’s professional judgment and independence in the design, conduct, or publication of research (Association of American Universities, Task Force on Research Accountability, 2001; APA, 2010a, Standard 1.03, Conflicts Between Ethics and Organizational Demands, and Standard 3.06, Conflict of Interest; NIH, Office of Extramural Research, 2002). Although conflict-of-interest dilemmas have been spotlighted in the media and scholarly journals, it is not widely addressed in psychology graduate training programs (Fisher, Fried, & Feldman, 2009) and university-affiliated research psychologists soon may find themselves in the type of conflict between ethics and the demands of private sponsors previously encountered by medical researchers. Conflicts between ethical obligations under an Ethics Code and private sponsor organizations may arise when psychologists’ research results are inconsistent with the commercial interests of the company funding their study. For example, when unanticipated patient risks emerge during clinical trials, sponsors may attempt to prevent psychologists from fulfilling their obligation to inform their IRB of the adverse events, in violation of federal regulations (NIH, 1998) and Ethics Code Standard 8.01, IRB Approval. When unanticipated risks to participants emerge during a clinical trial, under Ethics Code Standard 3.04, Avoiding Harm, and federal regulations requiring data safety monitoring plans and actions (DHHS, 2005, 45 C.F.R. § 46.111), psychologists are obligated to take appropriate steps to minimize such risks. Such steps may involve actions to which the sponsor company objects, including terminating or modifying the study or from informing participants about new concerns that may influence their willingness to continue in the research. Sponsors also may attempt to prevent publication of data that jeopardizes the marketability of their product (Thompson, Baird, & Downie, 2001) or exert pressure on the psychologists to falsify results in direct violation of Ethics Code Standard 8.10, Reporting Research Results, and federal prohibitions against fabrication and falsification of data (Public Health Service [PHS], 2000a).

Regulation

The NIH Office of Extramural Research requires every institution receiving research PHS grants to have written guidelines for the avoidance and institutional review of conflict of interest. These guidelines must reflect state and local laws and cover financial interests, gifts, gratuities and favors, nepotism, political participation, and bribery. In addition, employees accepting grants or contracts are expected to be knowledgeable of the granting and contracting organization’s conflict of interest policy and to abide by it (PHS, 2000b).

Organizational Requirements

When faced with conflicts between ethics and organization demands, Ethics Code Standard 1.03
requires that psychologists explain to the sponsor their ethical obligations under the Ethics Code, including their commitment to participant protection and the responsible conduct of research. In doing so, they must develop a plan and take actions to resolve the conflict in a manner that permits adherence to the Ethics Code. Psychologists and their universities also should be alert to research contracts that include nondisclosure or confidentiality agreements that create additional barriers to resolution of such conflicts (Fisher, 2012).

The APA Task Force on External Funding
As summarized by Pachter, Fox, Zimbardo, and Antonuccio (2007), the APA Task Force on External Funding generated a detailed history of conflicts of interest in related fields along with specific recommendations for psychology, including the following:

- When research is industry sponsored, psychologists should ensure that they have input into study design, independent access to raw data, and a role in manuscript submission.
- Full public disclosure regarding financial conflicts of interest should be included in all public statements.

APA Publication Manual Policies
APA also has specific conflict of interest policies for publication of research. The APA Editor’s Handbook: Operating Procedures and Policies for APA Publications (APA, 2006, Policy 1.03) requires that journal reviewers and editors avoid either real or apparent conflicts of interest by declining to review submitted manuscripts from recent collaborators or students, members of their institutions, or work from which they might obtain financial gain. When such potential conflicts of interest arise or when editors or associate editors submit their own work to the journal they edit, the Editor’s Handbook recommends that the editor (a) request a well-qualified individual to serve as ad hoc action editor, (b) set up a process that ensures the action editor’s independence, and (c) identify the action editor in the publication of the article. APA also requires all authors to submit a Full Disclosure of Interests Form that certifies whether the psychologist or his or her immediate family members have significant financial or product interests related to information provided in the manuscript or other sources of negative or positive bias (APA, 2010b).

Documentation and Reporting of Research Results
Psychologists conducting research must create and maintain records in a manner that allows for replication of the research design by the psychologist or others. This includes an adequate description of recruitment procedures, documentation of informed consent, relevant demographic characteristics of participants, data collection procedures, materials or equipment, and data analysis strategies. Raw data should be stored in a form accessible to analysis or reanalysis by the psychologist or other competent professionals who seek to verify substantive claims (see Ethics Code Standard 8.14, Sharing Research Data for Verification).

The number of years of retention of raw data for investigators will vary with state law, federal regulations, and institutional policies. Federal regulations (Office of Management and Budget, 1999) and PHS Grants Policy (NIH, 2001) require that data generated through federal support be maintained by institutions for at least a period of 3 years following the completion of the project and the filing of the final progress and financial reports. The number of years may be longer if a patent is involved. Specific record-keeping requirements for IRBs include maintenance of copies of the scientific proposal, the informed consent document, summaries of the project, financial reports, and reports of injuries or other serious adverse events. Authors of articles published in APA journals must have their raw data available for at least 5 years after the date of publication (APA, 2010b).

Research Costs
Under Ethics Code Standard 6.01, Documentation of Professional and Scientific Work and Maintenance of Records, principal investigators on federally funded grants must create and maintain accurate records of costs associated with the research, including participant compensation, research assistant salaries, investigators’ percent effort working on the grant, equipment, travel, and other supplies necessary to
conduct the research. For federally funded projects, IRBs are subject to federal grants compliance and oversight. For each grant, the IRB must account for cost allocations and cost transfers, time and effort reporting, allowable grant charges, and unobligated balances.

Honest Reporting Research Results
Ethics Code Principle C, Integrity, underscores the centrality of accuracy and truthfulness in the conduct of science. Fraud in research is one of the most serious forms of scientific misconduct because it disrupts the scientific process, dilutes community confidence in the integrity of science, and can lead to misinformed interventions and policies. Psychologists do not falsify, make up, alter, or distort the responses of human participants or animal subjects or the results of data analysis. This standard is not limited to published reports and applies to the fabrication of data in journal entries or intentional manipulation of the data collection process that would lead to a false report. Psychological scientists also should refer to Ethics Code Standard 5.01, Avoidance of False or Deceptive Statements, for additional prohibitions against publishing or presenting research findings psychologists know are false (Fisher, 2012).

The research design, measurement tools, and analytic strategies selected by an investigator may lead to erroneous conclusions based on honest differences in interpretation, chance responding, or extraneous influences that are revealed only when new techniques are used to examine the hypothesis tested. Erroneous conclusions about natural phenomena based on methodologically sound research designs are a natural part of the scientific process and are not unethical. A cornerstone of scientific progress is the process of self-correction in which the validity of results obtained in a single experiment can be confirmed or refuted following replication by others within the scientific community. Accurate reporting of research is essential to this process because it enables others to critique, replicate, dispute, and expand on the methods and interpretations reported (Fisher, 2012).

The purpose of Ethics Code Standard 8.10, Reporting Research Results, is to safeguard the self-correction process by requiring that psychologists take steps to correct errors in published reports that compromise the readers’ ability to replicate the research design or interpret the results because the methodology, data, or statistical analysis was described incorrectly. Informing the journal editor or publisher about the error and requesting a published correction can comply with this standard. The use of the phrase “reasonable steps” recognizes that investigators have limited control over editors or publishers who refuse to publish corrections (Fisher, 2012). (More information on issues regarding scholarship and publication can be found in Chapter 15 of this volume.)

MULTICULTURAL ETHICAL COMPETENCE
Ethical decision making in diverse cultural venues must be sensitive to cultural attitudes toward individual autonomy and communal responsibility; historical and contemporary discrimination within society and psychology as a discipline; sociopolitical factors influencing definitions of race and ethnicity; and variations in immigration history, acculturation, cultural or ethnic identity, language, and mixed race or ethnic heritage (Lyon & Cotler, 2007; Ponterotto, Casas, Suzuki, & Alexander, 2001; Sue & Sue, 2003; Trimble & Fisher, 2006). Multicultural responsibility requires “a fusion of personal and professional commitments to consider culture during ethical encounters” (Ridley, Liddle, Hill, & Li, 2001, p. 176). This section describes how Fisher (2012) has applied the ethical decision-making and goodness-of-fit framework to identify key questions research psychologists may consider as a means to acquire the attitudes and knowledge essential to the responsible conduct of multicultural research.

Multicultural Ethical Commitment
Multicultural ethical commitment requires a strong desire to understand how culture is relevant to the identification and resolution of ethical problems as they emerge in research involving diverse populations. It demands a moral disposition and emotional responsiveness that moves psychologists to explore cultural differences and creatively apply the Ethics Code to each cultural context. Cultivation of these
competencies thus includes motivation to conscientiously, prudently, and with caring discernment consider the influence of culture in psychologists’ research.

The desire to ensure that cultural sensitivity is integrated into ethical decision making requires a willingness to reflect on how institutional and scientific culture influence the way ethics is conceived in evaluating research risks and benefit (Fisher, 1999). Furthermore, multicultural ethical competence entails recognition of harms that psychological science can exert on culturally diverse groups by invalidating their life experiences, defining their cultural values or differences as deviant, and imposing the values of dominant culture upon them (Fisher, 1999; Fisher et al., 2002; Fowers & Davidov, 2006; Prilleltensky, 1997; Trimble & Fisher, 2006). In psychological research, multicultural ethical commitment involves the motivation to

- critically examine moral premises in the discipline that may largely reflect the scientific establishment’s conceptions of research risks and benefits;
- question “deficit” and “ethnic group comparative” approaches to understanding cultural differences;
- when appropriate, address the reality and impact of racial and institutional discrimination in the lives of cultural minorities in research measures and designs;
- avoid conceptually grouping members of ethnic minority groups into panethnic categories (e.g., Hispanic) that may not do justice to within-group differences (e.g., Puerto Rican, Dominican, Mexican); and
- develop the flexibility required to respond to rapid cultural diversification and fluid definitions of culture, ethnicity, and race.

Multicultural Ethical Awareness

Multicultural ethical commitment is just the first step toward multicultural ethical competence. Good intentions are insufficient if psychologists fail to acquire relevant knowledge about cultural differences and how they may affect the expression of and solutions for ethical problems. To develop culturally valid research designs and participant protection procedures, psychologists can make efforts to become familiar with multidisciplinary sources of research that may include an understanding of the following:

- the history of ethical abuses of cultural minorities in the United States and how this may exacerbate disparities in mental health care, employment, criminal justice, and involvement in psychological research;
- the impact on mental health of historical and contemporary discrimination in employment, education, housing, and other areas;
- cultural and contextual factors that may facilitate or interfere with psychological well-being or responsiveness to intervention research participation;
- scientific, social, and political factors influencing the definitions of race, ethnicity, and culture and how these may serve as barriers to conducting research in ways that that protect participants’ rights and welfare;
- within-group as well as between-group differences that may be obscured by cultural stereotypes in society and within the discipline of psychology;
- knowledge and skills in constructing and implementing culturally valid and language appropriate informed consent, recruitment, confidentiality, and dissemination policies; and
- knowledge of relevant ethical standards in the Ethics Code and organizational guidelines relevant to multicultural ethical competence in research and practice.

Goodness-of-Fit Ethics and Multicultural Ethical Decision Making

Multicultural ethical commitment and ethical awareness are essential but not sufficient to ensure ethical resolution of multicultural challenges. Given the dynamic nature of individual, institutional, and sociopolitical concepts of race, culture, and ethnicity, ethical decision making across different cultural contexts can be informed but may not be resolved by previous approaches to ethical problems. Many multicultural ethical challenges are unique to the culture, the salience of the culture for a particular
individual in a particular context, other within-
culture individual differences, the community from
which participants are recruited, and the goals of
that activity. Multicultural ethical decision making
includes (a) creating a goodness of fit between the
cultural context and the psychologist’s work setting
and goals and (b) engaging in a process of colearning
that ensures this fit (Fisher & Ragsdale, 2006).
Applying goodness-of-fit ethics to multicultural
contexts requires reflection on the following
questions:

- What are the cultural circumstances that might
  render individuals more susceptible to the
  benefits or risks of the intended psychological
  research?
- Are cultural factors under- or overestimated in
  the research plan?
- Do psychologists and cultural groups with whom
  they work have different conceptions of research
  benefits?
- Are traditional approaches to informed consent
  and confidentiality protections compatible with
  the values spirit, collectivity, and harmony char-
  acteristic of some ethnocultural populations?
- Are there aspects of the research setting, recruit-
  ment procedures, or informed consent that are
  “misfitted” to the competencies, values, fears,
  and hopes of research participants?
- How can the setting (including the aims and pro-
  cedures to accomplish these aims) be modified
  to fit the requirements of culturally sensitive and
  responsibly conducted psychology?
- How can investigators research involve partici-
  pants and their communities in discussions that
  will illuminate the cultural lens through which
  they view the research?

Culture is a dynamic construct influenced by an
ever-changing sociopolitical landscape. Ethical deci-
dion making that includes multicultural commit-
ment and awareness can help research psychologists
avoid cultural misimpressions and biases in their
work. Openness to learning from and collaborating
with stakeholders through the process of colearning
can help psychologists implement and monitor
the cultural adequacy of ethical decisions and
make appropriate adjustments when necessary.

Multicultural ethical competence requires a process
of lifelong learning that enables psychologists to
make ethical decisions that reflect and respect the
values of the discipline of psychology and the values
of those participating in the research.

CONCLUSION
Ethical decisions are not singular or static. They
involve a series of steps, each of which will be deter-
mined by the consequences of previous steps. Evalu-
ation of alternative ethical solutions should take a
narrative approach that sequentially considers the
potential risks and benefits of each action. Under-
standing of relevant laws and regulations as well as
the nature of institutions, companies, or organiza-
tions in which the research will take place is similarly
essential for adequate evaluation of the reactions and
restraints imposed by the specific ethical context.

Ethical commitment and well-informed ethical
planning will reduce but not eliminate ethical chal-
lenges that emerge during the course of research.
There is no ethical menu from which the right ethi-
cal actions simply can be selected. Many ethical
challenges are unique in time, place, and persons
involved. The very process of generating and evalu-
ating alternative courses of action helps place in
vivid relief the moral principles underlying such
conflicts and stimulates creative strategies that may
resolve or eliminate them.

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