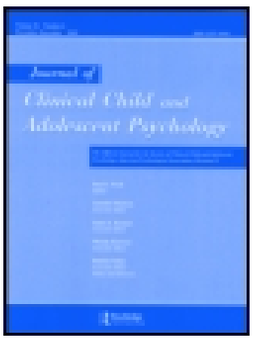

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Informed Consent and Clinical Research Involving Children and Adolescents: Implications of the Revised APA Ethics Code and HIPAA

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In 2003, 2 new sets of rules and regulations affecting the conduct of clinical research involving children and adolescents went into effect: the revised American Psychological Association's (APA) Ethical Principles of Psychologists and Code of Conduct (APA, 2002; effective June 1, 2003) and the Privacy Rule (45 CFR Part 160 and A and E of Part 164; effective April; 14, 2003) of the Health Insurance Portability and Accountability Act (HIPAA: Public Law 104–191). This article highlights those APA ethical standards and HIPAA regulations relevant to clinical research involving children and adolescents and discusses how psychologists can apply these rules in ways that will ensure ethical and legal compliance.

Since its inception in 1953, each revision of the American Psychological Association (APA) Ethics Code has been driven by the evolving roles and responsibilities of psychologists within a constantly changing moral, cultural, economic, political, and legal landscape. Several disciplinary and public trends relevant to informed consent to research influenced the latest revision of the Ethics Code (APA, 2002). These trends include (a) the advent of Internet-mediated research and the use of other electronic media for conducting, storing, and disseminating research; (b) increased sensitivity to the research needs of culturally and language-diverse populations; (c) the need for greater harmonization between APA standards for research and federal policies for the protection of human participants (Department of Health and Human Services, 2001); and (d) the shift from paternalistic to autonomy-based public attitudes and federal regulations regarding informed consent, patient privacy, and patient access to health records for the public in general and minors in particular (Fisher, 2003c).

In the 2002 Ethics Code, the informed consent standards specific to research were expanded to provide greater specification of information that must be included in informed consent in general and in intervention research in particular, as well as when informed consent to research can be waived. Other revisions in the Ethics Code relevant to clinical research include explicit statements that informed consent is required for the conduct of research via electronic transmission; expanded ethical obligations for children, adolescents and other persons who are legally incapable of giving informed consent; and new requirements for psychological activities involving the use of interpreters.

The completion of the 2002 revision of the APA Ethics Code coincided with the adoption of federal regulations governing the creation, use, storage, and disclosure of health information. The timing of the revision and the effective date of this set of laws, known as Health Insurance Portability and Accountability Act (HIPAA), provided the APA Ethics Code Task Force the opportunity to consider the effect of the HIPAA on activities conducted by psychologists (Fisher, 2003c). This article highlights the major enforceable 2002 Ethics Code standards and the HIPAA regulations that psychologists conducting clinical research involving children and adolescents need to be familiar with to ensure that informed consent practices comply with professional and federal rules.

When Is Clinical Research Governed by HIPAA?

Successful compliance with APA ethical standards for informed consent must include an understanding of the relation between HIPAA (Public Law 104–191) and clinical research. In 1996, HIPAA was approved by Congress to create standardized formatting of health care records across providers, institutions, localities, and states. Recognizing that uniform standards for creating, transmitting, and storing of health care records increased the potential for privacy violations, Congress included HIPAA Privacy Standards (45 CFR

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Part 160 and Subparts A and E of Part 164; effective April 14, 2003) to limit the use and release of health information, give patients greater access to and control of their records, and establish legal accountability and penalties for unauthorized use and disclosure of individually identifiable health information.

Definitions

Understanding the implications of HIPAA for clinical research involving children and adolescents requires familiarity with HIPAA terminology and definitions.

Protected health information (PHI). HIPAA regulations apply only to PHI. PHI 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 a covered entity. Research data derived from diagnostic or treatment information created by an investigator or acquired from existing health care records would be considered PHI.

Covered entity. A covered entity is defined as a health plan, a health care clearinghouse, or a health care provider that transmits any health information in electronic form in connection with financial or administrative activities related to health care. Investigators who are responsible for data collection involving mental health assessments or treatment that will be entered into a research participant's health care records or used for health care decisions is a covered entity. Health care organizations or independent practitioners from whom health care data may be obtained are also covered entities.

Definitions of *treatment* and *research*. HIPAA defines treatment as "the provision, coordination, or management of health care and related services by one or more health care providers, including the coordination or management of health care by a health care provider with a third party; consultation between health care providers relating to a patient; or the referral of a patient for health care from one health care provider to another" (45 CFR 164.501). Research is defined as "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge" (45 CFR 164.501).

Research governed by HIPAA. Research in general is not considered a HIPAA-covered function. However, research activities that involve a covered entity or include treatment, payment, or the administration of health care operations must adhere to relevant HIPAA regulations. Psychologists conducting research involving direct delivery of services or assessments and diagnoses that will be used for a patient's treatment decisions should consider themselves covered entities under HIPAA. Psychologists who are not directly involved with patient care but are involved in the design or analysis of data for intervention or quality improvement research for a health care facility or other covered entity must use HIPAA-compliant procedures appropriate for that entity. Investigators who are not involved in direct delivery of services or intervention research but who provide consultation to or plan to use in their research PHI created by a covered entity must provide assurances of HIPAA compliance to the covered entity.

HIPAA permits institutions to segregate non-health care and health care related functions. However, constructing such institutional policies in ways that are HIPAA compliant are difficult. Thus investigators who work in academic settings affiliated with a medical institution or other health care facility must consult with their institution's legal counsel to determine whether, irrespective of their specific research activities, they are subsumed under the institution's HIPAA umbrella (Barnes & Kulynych, 2003).

General APA Ethics Code Standards for Informed Consent

The 2002 APA Ethics Code used some of the language in the 1992 Code's Standard 6.11, Informed Consent to Research (APA, 1992), to create a new standard applicable to all psychological activities, Standard 3.10, Informed Consent (APA, 2002).

Guardians and Adolescents With Adult Legal Status

Standard 3.10a applies to informed consent involving adults, guardians of minors, and minors who have adult legal status. In this latter category are emancipated and mature minors. *Emancipated minor* is a legal status conferred on persons who have not yet attained the age of legal competency as defined by state law but are entitled to treatment as if they had such status by virtue of assuming adult responsibilities, such as self-support, marriage, or procreation. *Mature minor* is someone who has not reached adulthood (as defined by state law) but who according to state law may be treated as an adult for certain purposes (e.g., consenting to treatment for venereal disease, drug abuse, or emotional disorders). Although an emancipated minor can independently provide his or her own consent for research participation, a mature minor is only consid-

ered to have autonomy in legally specified situations that are unique to each state.

State and federal law. Investigators working with adolescents need to be familiar with both state laws and federal requirements governing parental rights in health care decisions affecting minors. In that states grant mature minors legal autonomy to make decisions concerning specific health care treatment, scholars have argued that it seems both reasonable and ethical to grant state-defined mature minors the same autonomy to decide whether to participate in research that provides the specific health care or examines mature minors' reasons for or reactions to seeking such treatments (Fisher, 2002; Fisher, Hoagwood, & Jensen, 1996; Rogers, D'Angelo, & Futterman, 1994). Researchers need to approach state definitions of mature minor with caution, however, because most state laws are silent on whether the designations of emancipated or mature minor extend to participation in research (English, 1995; Santelli et al., 1995).

Language

Under Standard 3.10a, psychologists obtaining consent must use language that is reasonably understandable to the individual. Psychologists must thus make efforts to ensure that terms used to describe research procedures and participant rights, including those associated with psychological assessments and treatments that are part of the research protocol, are compatible with the individual's experience, education, and language use. Psychologists must also use appropriate translations of consent information for individuals for whom English is not a preferred language or who use sign language (APA, 1993). When conducting research involving children and adolescents from non-English language populations, clinical investigators 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, Hoagwood, Boyce, Duster, et al., 2002).

Use of interpreters. Clinical investigators may use the services of interpreters to obtain informed consent in the language in which the participant is proficient. For the first time, the APA Ethics Code includes two standards stipulating psychologists' obligations under these circumstances: Standards 2.05, Delegation of Work to Others and 9.03c Informed Consent in Assessments. When delegating informed consent responsibilities to an interpreter, psychologists must ensure that the interpreter is competent to express consent-relevant terms appropriate to the participant's and guardian's language preferences and proficiencies as well as the participant's developmental level. The APA Ethics Code also requires that interpreters be adequately trained in the procedures necessary to protect the confidentiality of data collected.

Having children or adolescents serve as interpreters to obtain parent permission is not desirable, because it may result in misinformation or undermine respectful parent–child relationships. Moreover, in small and cohesive ethnic communities, individuals qualified to serve as interpreters may have other role relationships with prospective participants and their families (Fisher et al., 2002). APA Standard 3.05, Multiple Relationships, is thus relevant to the informed-consent process: When selecting interpreters, investigators must determine whether personal relationships between the interpreter and participant could be exploitative or otherwise harmful.

Research Involving Legal Minors

As in the earlier 1992 Ethics Code, under the new Ethics Code, when participants are legal minors, psychologists must obtain permission from a legally authorized person, give the child or adolescent participant an appropriate explanation of the research, and obtain the participant's assent. New to the ethical standards is the requirement that investigators obtaining assent must also consider the child's or adolescent's "preferences and best interests" (Standard 3.10b), indicating that although in most cases psychologists respect a child or adolescent's right to dissent from participation, this right can be superceded if failure to participate deprives the individual of psychological services necessary to protect or promote his or her welfare.

Child assent. Most children and adolescents under 18 years of age do not have the legal right to provide independent consent to participate in clinical research. In recognition of their rights as developing persons, APA Standard 3.10b requires that, following an appropriate explanation of the nature and purpose of the research and the right to decline or withdraw from participation, psychologists seek children's and adolescents' assent. The term *appropriate explanation* used in Standard 3.10b to describe assent procedures indicates that the language used to explain procedures to minors must be appropriate to their developmental, reading, and educational levels, and, if relevant, to aspects of their psychological disorder that might impair understanding or decisional capacity.

A small but growing literature suggests the ability to understand research procedures and research rights do not reach adult levels until mid- or late adolescence (Belter & Grisso, 1984; Bruzzese & Fisher, 2003; Geller, Tambor, & Bernhardt, 2003; Hurley & Underwood, 2002; Olechnowicz, Eder, Simon, Zyzanski, &

Kodish, 2002; Ruck, Abramovitch, & Keating, 1998). However, despite cognitive and experiential immaturity, once children have developed adequate communication skills, their silence or failure to object to research should not be construed as assent nor should their nonadult status and assent vulnerabilities be used to justify rejecting their autonomy rights. Rather, psychologists should strive to create a goodness-of-fit between children's and younger adolescents' maturing skills and the research context by approaching assent as a process of research education as well as information to optimize decision making and promote their nascent autonomy (Fisher, 2003b).

Guardian permission. When conducting research involving children or adolescents, psychologists must also obtain appropriate permission from a legally authorized person. Psychologists who do not obtain the active permission of guardians or who use passive consent procedures (sending guardians forms asking for a response only if they do *not* wish their child to participate in a school-based intervention program or research study) violate this standard except "when consent by a legally authorized person is not permitted or required by law" (Standard 3.10b), or when the activities meet other conditions for dispensing with consent (Standard 8.05, Dispensing With Informed Consent for Research). Research psychologists should be aware that passive consent procedures are often viewed negatively by parents and teenagers alike, who perceive it as a deceptive attempt to "hook kids into participating" when parents may not really want to give permission (Fisher, 2002).

Foster children and juvenile detainees. Psychologists conducting research involving children and adolescents in the foster care system or juvenile detention centers must carefully determine who has legal responsibility for substitute decision making. Because the legal guardianship of foster children and juvenile detainees often changes over time, psychologists conducting clinical research with these populations should frequently check the guardian status of participants and, when feasible, obtain permission from legal guardians as well as those adults who share major responsibility for the child's welfare (see also federal guidelines for research involving wards of the state, Department of Health and Human Services, 2001, 45 CFR 46.409).

Best interests of the child. Under APA Standard 3.10b psychologists must consider the "best interests" of persons who are legally incapable of giving informed consent. The requirement for guardian permission assumes that participants come from a reasonably secure family setting in which the children or adolescents and their guardians share loving relationships (Gaylin & Macklin, 1982). However, the mental health problems and high-risk physical and social conditions that bring children and adolescents to the attention of clinical scientists (e.g., psychopathology, child abuse, health-compromising sexual behaviors, drug abuse, juvenile detention) may in themselves place a child in jeopardy or violate a teenager's privacy rights if guardian permission is obtained. In such cases, guardian permission may not be in a child's or teenager's best interest, not permitted, or not required by law. In these instances, Standard 3.10b requires psychologists take reasonable steps to protect the minor's rights and welfare. When research involves young children, such steps would include working with courts or social agencies to identify an adult with legal guardianship for the child. In cases involving mature or emancipated minors or emergency services, the appointment of a consent advocate can protect the adolescent's rights and welfare by verifying his or her understanding of assent procedures, supporting the adolescent's preferences, ensuring participation is voluntary, and monitoring reactions to psychological procedures (Department of Health and Human Services, 2001, 45 CFR 46.408c; Fisher et al., 1996).

Implications of HIPAA. HIPAA requires that if a person has legal authority to act on behalf of a minor in making health care decisions, a covered entity must treat such a person (called a *personal representative*) as the individual. Exceptions are permitted if there is reason to believe the patient or participant has been abused or is endangered by the personal representative or that treating the individual as a personal representative would not be in the best interests of the patient or participant (45 CFR 164.502g). This requirement refers to parents who are generally recognized as personal representatives of their minor children and court-appointed guardians or holders of relevant power of attorney.

Appropriate Documentation of Informed Consent

Standard 3.10d adds a new requirement that documentation of informed consent or assent from an individual and permission by a legal guardian or substitute decision maker has been obtained. In most instances, emancipated or mature minors, older children, and legal guardians of minor children will sign consent, assent, or permission forms. However, according to Standard 3.10d, oral consent can be appropriate when, for example, obtaining a young child's assent, working with illiterate populations, or there is concern that confidentially may be at risk (i.e., in war-torn countries in which consent documents may be confiscated by local authorities). In these situations, documentation can be a note in the psychologist's records.

Appropriate documentation can also be related to legal requirements. For example, HIPAA requires that all valid patient or participant authorizations (discussed later) for the use and disclosure of PHI must be signed and dated by the individual or the individual's personal representative, for example, the minor's guardian (45 CFR 164.508[c][1][vi]).

APA Informed Consent Standards Specific to Research

Informed consent requirements most relevant to clinical research are listed in Standard 8.02 of the APA Ethics Code. Standard 8.02a includes an expansion of the general requirements for informed consent for research that appeared in the 1992 Ethics Code. Standard 8.02b is a new standard that specifically regulates the behavior of psychologists conducting behavioral, psychosocial, biomedical, psychopharmacological, or community intervention research.

Describing the Purpose and Nature of Intervention Research

In general, child and adolescent participants and their legal guardians must be given information and the opportunity to ask questions about the purpose, duration, procedures, foreseeable risks, potential benefits, and compensation involved in participation sufficient to make an informed decision. When conducting intervention research, psychologists must clarify the "experimental nature of the treatment" (Standard 8.02b). Accordingly, psychologists must take reasonable steps to communicate to children, adolescents, and their guardians that unlike individualized treatment provided by a hospital or independent practitioner, (a) the primary purpose of the research is to determine whether a treatment works or how it works in comparison to another treatment and (b) that "experimental" treatment does not mean "better" treatment with known direct benefits for participants (Fisher, 2003c). This standard does not prevent psychologists from describing potential direct benefits of participation, such as (a) comprehensive psychological assessment and monitoring, (b) benefits of the experimental treatment if it proves effective during or following the conclusion of the study, or (c) treatment referrals.

Other additions to the APA ethical standards for informed consent to intervention research include requiring investigators to adequately inform participants and their legal guardians about the nature, benefits, and risks of both the experimental and control conditions, including relevant explanations of standard treatments offered at the health facility where research is conducted, treatment-as-usual in the community, different variations of the experimental treatment, or no treatment. Psychologists are also required to provide clear explanations of the way in which children or adolescents will be assigned to different arms of a clinical trial, especially when random assignment will determine the participant's treatment. Informed consent for studies using single- or double-blind procedures should describe the extent to which members of the research team, parents, and participants will know the group to which the participant has been assigned and steps that will be taken to determine if and how the blind will be broken if the participant's condition appears to deteriorate.

The Voluntary Nature of Participation

Under Standards 8.02a and 8.02b, participants and their legal guardians must be informed that they will not be penalized for declining participation, especially when they may have reason to believe that dissent will result in adverse consequences. For example, parents of children or adolescents who apply for or who already receive services at the study site may fear that failure to participate will result in deterioration or removal of existing services. Informed consent procedures must thus (a) assure patients currently receiving services and their guardians that dissent will not disrupt ongoing treatment and (b) inform individuals new to the treatment facility of nonexperimental alternative services when they are available (Fisher, 2003c).

Multiple relationships and conflict of interest. Two additional standards in the APA Ethics Code are helpful in alerting psychologists to competing role relationships and interests that might compromise the voluntary nature of research participation. Psychologists conducting clinical research often serve a dual provider–investigator role in relation to research participants and their guardians. According to Standard 3.05, Multiple Relationships, psychologists should refrain from entering into a multiple relationship if it could be reasonably expected to impair the psychologist's objectivity, competence, or effectiveness or otherwise risk exploitation or harm to the individual with whom the relationship exists.

Clinical researchers often have both an interest in the welfare of patients or participants as well as an interest in participant recruitment and retention as a means of successfully implementing the research and maintaining or obtaining additional funding for the research. For the first time, the 2002 APA Ethics Code includes a standard on Conflict of Interest (Standard 3.06) under which psychologists must refrain from taking on a professional role when personal, scientific, or financial interests expose the person with whom the professional relationship exists to harm or exploitation. In light of both these standards, psychologists can help to ensure the voluntary nature of participation in re-

search by obtaining consent from a neutral party and informing prospective participants and their guardians about these various relationships and interests and stipulating how the right to dissent and withdraw from participation will be assured without penalty or coercion.

Reimbursement, Compensation, Incentives, and Services

Under Standard 8.02a, the conditions under which children or adolescents and their guardians will qualify for reimbursement or compensation for participation in nonintervention clinical studies must be fully described. In determining appropriate payments or nonmonetary inducements for research participation, psychologists must make reasonable efforts to avoid offering excessive or inappropriate inducements likely to coerce participation (Standard 8.06a, Offering Inducements for Research Participation).

Standard 8.06b permits psychologists to link involvement in nontherapeutic research with treatment that immediately follows. 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 et al., 2002). 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 (Fisher, 2003c).

The cost of treatments provided in intervention research may be charged to participants' families, provided at no cost through federal or corporate research funding, or billed through a participant's health plan. Understanding the financial costs and the extent to which third-party payors will be aware of diagnoses and services received during a research study is essential for informed decision making. Consulting with families from the population who will be recruited for research participation about the affect of different types of research compensation on participants and guardians can help investigators and their institutional review boards (IRBs) determine the extent to which cash or nonmonetary compensation is fair or coercive (Fisher, 2002, 2003a).

Confidentiality

Disclosure of confidential information revealed during participation in clinical research can result in involvement of child protection services in family life, have consequences for future health insurance eligibility, or expose participants and their parents to criminal or civil liability or social damage. Informed-consent procedures must provide a clear explanation for children, adolescents, and their guardians of the extent and limits of confidentiality, including (a) whether investigators must comply with reporting requirements such as mandated child abuse reporting or duty-to-warn laws, (b) the investigators' 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) the extent to which the method of data collection itself may limit the extent of confidentiality protections as may be the case when research is conducted via the Internet. Investigators should also inform participants and parents if they have received a Certificate of Confidentiality (Public Health Service Act, Section, 301[d], 42 U.S.C. Section 241[d]) protecting research records from most types of subpoenas (Fisher, 2002, 2003a; Fisher, Higgins-D'Alessandro, Rau, Kuther, & Belanger, 1996). When clinical research comes under HIPAA, protections under the Certificate of Confidentiality cannot generally be overridden; although the Department of Health and Human Services may compel disclosure of the records for auditing purposes when the research is federally funded (Barnes & Kulynych, 2003).

HIPAA notice of privacy practices. When health care will be provided as part of a research protocol, HIPAA requires that prospective participants and their guardians receive a Notice of Privacy Practices that describes the psychologist's policies for use and disclosure of PHI, and the patient's and guardian's rights and investigator's obligations under the Privacy Rule (45 CFR 164.520). In most instances, the Notice will be given to prospective participants or their legal guardians at the same time as informed consent is obtained, because the Notice provides information relevant to the scope and limits of confidentiality (Fisher, 2003c).

The Notice must be provided to participants and guardians in written form and separate from other informed consent procedures or documents.

HIPAA authorization to use PHI for research. To create, use, or disclose PHI for research purposes, a covered entity must receive a signed authorization from the prospective participant or a legal guardian limited to the specific research project (45 CFR 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 (45 CFR 164.508[b][3][i]). In addition, unlike nonresearch treatments, investigators who conduct clinical trials can condition provision of treatment within the research protocol based on authorization (45 CFR164.508[b][4][i]).

HIPAA authorization is also required for psychologists conducting records research on PHI collected by other persons or institutions that are covered entities. With few exceptions, when records contain identifiable health information, covered entities cannot give investigators access without a patient- or guardian-signed authorization that details the specific information that can be used and that states that its use is limited to the specific research purposes and to the specific investigative team for a specific period of time.

Use of PHI for research without authorization. Under HIPAA, PHI may be used for research purposes without participant or guardian authorization if the covered entity receives written documentation that waiver of patient authorization has been approved by an investigator's IRB 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 the privacy rights and the welfare of the individuals; (c) the research could not practicably be conducted without access to the PHI and without the alteration or waiver; (d) the privacy risks are reasonable in relation to the anticipated benefits to science and, if any, to the individuals; (e) there is an adequate plan to protect the identifiers from improper use and disclosure; and (f) there are adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, except as required by law or for authorized oversight of the research project (Rules for Research are under 45 CFR 164.501, 164.508[f], 164.512[i]).

The HIPAA regulations are consistent with Standard 8.05, Dispensing with Informed Consent for Research (APA, 2002), which permits investigators to dispense with informed consent for research in three well-defined contexts predicated on the condition that the research will not create distress or harm: (a) the study of normal educational practices, (b) anonymous data, and (d) the study of job or organization effectiveness. According to the standard, psychologists may also dispense with informed consent to research when a consent waiver is permitted by law or federal or institutional regulations. In such instances, researchers bear the burden of demonstrating that such conditions are met. Clinical researchers should keep in mind that decisions regarding whether their research meets the permitted contexts for dispensing with informed consent must be approved by their IRB (see Standard 8.01, Institutional Approval, APA, 2002).

Under HIPAA, covered entities who are not themselves conducting research may also waive authorization for the use and disclosure of PHI for research by an investigator under the following conditions (45 CFR 164.512[i]): (a) Information is de-identified by the covered entity (de-identification has very specific requirements under HIPAA [see 45 CFR 164.514], and clinical investigators need to ensure that records they seek to obtain are appropriately de-identified); (b) the PHI is reviewed for the sole purpose of preparing a research protocol, the information is necessary for the research purposes, and the PHI is not removed from the covered entity's premises; (c) research is on decedent's information; (d) disclosure is restricted to a limited data set (as specifically defined by HIPAA 45 CFR 164.513[e][2]) and the investigator enters into a "data use agreement" with the covered entity; or (e) the investigator signs a business associate contract with a covered entity to use PHI to conduct data analysis or quality assurance or other activities on behalf of the covered entity and to comply with all HIPAA regulations (45 CFR 160.103 and 164.504[e][1]).

Informed Consent to Research Involving Children and Adolescents: A Respectful and Continuing Process

The moral claims of children and adolescents on research psychologists are no different from those of adults. They have the right to assume scientists will communicate with them honestly, do them no harm, treat them fairly, and protect their autonomy and privacy. Respectful and compassionate assent contexts require understanding children's and adolescents' ways of thinking, assent strengths and weaknesses, life experiences, and practical concerns and construction of developmentally fitted efforts to ensure these claims are met (Fisher, 2003b). For example, children have limited experience exercising their rights in response to requests from adult authority figures, especially within academic, health care, or other unfamiliar settings. Constructing procedures that concretely demonstrate dissent will not be penalized and providing opportunities to practice decision making can optimize voluntary participation choices. In addition, the informed-consent process for clinical research involving children and adolescents must be viewed as a continuous process. In long-term treatment and longitudinal research, investigators should strive to construct re-consent procedures that fit children's and adolescents' maturing decisional capacities.

Child and adolescent autonomy need not be conceptualized as isolated or isolating (Walker, 2002). Like all persons, children and adolescents are connected to others in relationships of dependency and trust. APA ethical standards and federal regulations governing research recognize that a minor's assent to research participation does not occur in a vacuum but within the context of federal, institutional, and family protections. Informed-consent procedures for clinical research thus need to reflect an increasingly personalized progression of child and adolescent protections acknowledging assent vulnerabilities while maintaining respect for children as developing persons (Fisher,

2003b). First, investigators, with their IRB's, determine whether the balance of research risks and prospective benefits are ethically justified for the clinical population to be recruited. Second, parents decide whether the risk–benefit balance is appropriate for their own child's unique characteristics and experiences. If parents give permission for research participation, the APA ethical standards then permit children and adolescents to decide whether they wish to participate in the research procedures and purposes, as they understand them. Creating opportunities for supported decision making involving parent–child discussion about clinical research can create assent contexts that minimize stress, optimize child and adolescent input into the participation decision, and ensure that participants' wishes and concerns are adequately communicated. Parental permission and developmentally fitted assent procedures that protect child and adolescent welfare and promote their maturing autonomy are thus essential to an informed-consent ethic of respect and care.

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