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Human Participants Challenges in Youth-Focused Research: Perspectives and Practices of IRB Administrators

Diane K. Wagener
RTI International
Rockville, Maryland

Amy K. Sporer
Health Research and Policy Centers
University of Illinois at Chicago

Mary Simmerling
Department of Philosophy
University of Chicago

Jennifer L. Flome and Christina An
RTI International
Washington, District of Columbia

Susan J. Curry
Health Research and Policy Centers
University of Illinois at Chicago

The purpose of this research was to understand institutional review board (IRB) challenges regarding youth-focused research submissions and to present advice from administrators. Semistructured self-report questionnaires were sent via e-mail to administrators identified using published lists of universities and hospitals and Internet searches. Of 183 eligible institutions, 49 responded. One half indicated they never granted parental waivers. Among those considering waivers, decision factors in-

Requests for reprints should be sent to Susan J. Curry, Health Research and Policy Centers, University of Illinois at Chicago, 1747 West Roosevelt Road, Room 558, M/C 275, Chicago, IL 60608. E-mail: suecurry@uic.edu

cluded research risks, survey content, and feasibility. Smoking and substance abuse research among children was generally considered more than minimal risk. These findings are consistent with those from a study conducted by Mammel and Kaplan (1995), which investigated IRB practices concerning protocols involving adolescent participants. IRBs and investigators need to become aware of regulations' flexibility to ensure adequate participant protection. Investigators need to limit jargon and assumptions about participants' understanding of research objectives.

Keywords: consent, human participants, IRB, waiver, youth

Many health risk behaviors begin in adolescence, including smoking and alcohol consumption, sexual activity, interpersonal violence, and lack of adequate exercise (Pastor, Makuc, Reuben, & Xia, 2002). Research with adolescents is critical to understanding and improving the present and future health status of the nation. However, there are notably fewer studies of adolescents than of adults for such important risk factors as smoking. For instance, see a recent review of 66 adolescent treatment outcome research projects by Sussman (2002) compared to an analysis of 3,000 adult studies in the U.S. Department of Health and Human Services (USDHHS) clinical practice guidelines (Fiori et al., 2000).

The conduct of youth-focused research faces a number of challenges. All research conducted or supported by the USDHHS is subject to regulations under the Federal Policy for the Protection of Human Subjects (2001), which specifies general requirements for the conduct, method of consent, and review of the research. This article addresses some challenges that institutional review boards (IRBs) encounter when evaluating research proposals involving youths as participants, particularly proposals that focus on illicit behaviors such as underage tobacco smoking. These federal regulations identify children as one of several vulnerable populations in need of additional protections. Other vulnerable populations are pregnant women (Subpart B) and prisoners (Subpart C; Federal Policy, 2001). Vulnerable populations include members of society who through economic, social, biological, or legal status may be more susceptible to inherent research pressures and thus may require special protection from research risks.

Although adolescents are not specifically mentioned in the federal code protecting human participants, they are included with children as "minors." Children are considered vulnerable in part because of the legal limitations on their autonomy, but also because of their presumed reduced capacity to understand and fully participate in the informed consent process (Federal Policy, 2001). Just as the conceptual understandings of both the legal context and cognitive maturity of children have been evolving, so also has the interpretation of the requirements included in Subpart D of the federal code (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1977; National Institutes of

Health [NIH], 1998). In 1995, Mammel and Kaplan conducted a survey of IRBs that indicated a broad spectrum of interpretations of these federal regulations. In the same year, a conference sponsored by the Society for Adolescent Medicine (1995) was convened to develop guidelines for adolescent health research. These guidelines were intended to benefit both IRB members and researchers. However, much controversy still exists regarding the interpretation and application of the regulations governing research with children (Dickey & Deatrick, 2000; Dickey, Kiefner, & Beidler, 2002; Ford, Thomsen, & Compton, 2001; Mammal & Kaplan, 1995; Muscari, 1998; Weddle & Kokotailo, 2002; Weithorn & Scherer, 1994; Wilfond, Geller, Lerman, Audrain-McGovern, & Shields, 2002).

The Institute of Medicine (IOM) recently released a report entitled, "The Ethical Conduct of Clinical Research Involving Children" (Field & Behrman, 2004, p. S-3). The report concluded that federal regulations regarding special protections for children are appropriate. However, it noted that there are problems with the regulations, due in part to the lack of data on implementation and compliance as well as variability in how IRBs and investigators interpret the criteria for approving research with children (Field & Behrman, 2004). The report cited a dearth of information about IRB programs and practices.

The federal regulations provide flexibility of interpretation, allowing IRBs to respond ethically to differing contexts. However, lacking precedence for research protocols involving children, IRBs appear to apply the regulations with strict adherence without making adequate use of this provision. Therefore, the challenge that IRBs face lies in the interpretation of the regulations while understanding the importance of research involving high-risk behaviors. Using tobacco smoking as an example, many parents and guardians of teens are unaware that their children smoke. Although most teens want to quit smoking, many would be deterred from participating in a smoking cessation study if they were required to obtain permission from their parents. This results in a failure to recruit sufficient numbers of teens for treatment evaluation, or in the recruitment of nonrepresentative samples of smokers. Both consequences limit our ability to identify effective youth smoking cessation treatments.

This report discusses comments provided by IRB administrators through a semistructured questionnaire to identify current actions of IRBs regarding three issues of research and consent involving children: waiver of parental permission, allowance of so-called "passive" consent, and determination of risk for smoking and substance abuse protocols. Further, the respondents were asked to discuss factors that played an important role in these discussions and to offer opinions about some of the most challenging issues in the review of research protocols involving children as participants and ways that the protocols could be improved. The responders for this report are from a representative sample of IRB administrators who were invited to share information for the study.

METHOD

Administrator Identification

We aimed to develop a broad list of IRBs representing universities, hospitals, state and local agencies, and independent and private nonprofit research organizations. We obtained data by sending e-mail surveys to individuals at institutions identified through three primary sources: the *U.S. News & World Report's* Best Colleges (purchased database index), the *U.S. News & World Report's* Best Hospitals (purchased database index), and an Internet search using IRB-related terms and relevant locality keywords (e.g., New York state). For one fourth of the institutions on the lists, each institutional Web site was reviewed to locate the e-mail address of the IRB administrator. Those institutions providing contact information were sent an e-mail questionnaire. Finally, the sample was enriched with seven additional institutions that had responded to a University of Illinois–Chicago survey of IRB reviews of proposed tobacco research. In total, 183 questionnaires were sent out.

An additional method of reaching potential respondents was posting an invitation on www.IRBforum.org, an IRB discussion and news forum Web site. Our posting included background information about the project, four sample questions, and contact information for those wishing to complete the full questionnaire. This method yielded five responses.

Questionnaire Description and Administration

Our semistructured questionnaire with an accompanying introductory letter was sent via e-mail. The letter informed potential respondents about the project, how they were selected, and the objectives of the survey. The letter also explained confidentiality procedures. Two methods of participation were offered—e-mail or telephone. The actual survey was included as a Microsoft® Word attachment to the e-mail. The RTI International IRB reviewed and approved the survey and related materials.

Questions elicited both forced-choice and open-ended responses covering three topic areas: (a) institution and IRB portfolio characteristics, (b) discussions of the board regarding specific youth research issues, and (c) advice and insight for researchers. In the first section, questions included type of research conducted by the institution, number of new protocols reviewed annually, and proportions of protocols involving children and nonmedical child interventions. *Nonmedical* research was defined as evaluation of health promotion and disease prevention programs; tobacco or substance abuse research, such as randomized trials and treatment program evaluations; or school-based evaluations or surveys. In the second section, questions about the discussions of the institution's IRB addressed the following issues: permissibility of parental waivers and passive consent, the interplay of state

laws and minor consent, state-specific requirements for template language, and the level of risk involved with smoking and substance abuse research. Although passive consent is not part of the federal regulations, it is a term commonly used in the research community. Passive consent refers to a process in which parents or guardians are provided with a letter that states the nature and purpose of the research and the potential enrollment of their children. If the parents or guardians do not want their children to participate in the research, they must respond to the letter indicating that they do not give their children permission to participate. Parents who do not actively refuse their children's participation are considered to provide passive consent. In essence, passive consent is the same as a waiver of parental consent. For this questionnaire section, respondents were first asked for a "yes" or "no" response and then asked to expound on their responses. The passive consent questions were added to the questionnaires administered after responses to the first 30 queries had been reviewed. Finally, in the third section, strictly open-ended responses were elicited regarding the challenges faced when reviewing pediatric research protocols, advice for investigators preparing IRB submissions dealing with children, and general insights into pediatric research.

RESULTS

Overall Findings

In total, 188 questionnaires were sent with 59 responding. Of these, 49 (26%) completed the questionnaire, 5 refused, and 5 were ineligible. The majority of the 49 respondents were IRB administrators associated with university or academic institutions (n = 36). Another 8 respondents represented hospitals. Consequently, the results do not represent governmental or nonprofit research organization IRBs.

Table 1 shows the characteristics of the review portfolios of these IRBs. More than 80% of the IRBs reported that they typically reviewed more than 100 protocols yearly. However, research protocols involving children were less than one fourth of all protocols received by most of the respondents (74%). Therefore, the respondents reflect IRBs whose protocols of research involving children, although not uncommon, are a minority of their IRB applications.

A majority of the responding IRBs reviewed social and behavioral research (n = 42), biomedical research (n = 29), or both. More than half of the respondents (Table 1) indicated that most of the protocols involving children fell into the nonmedical class, whereas only 7 respondents (4 medical centers and 3 independent review boards) indicated that fewer than 5% of the protocols involving children reviewed by their IRB were nonmedical.

About half of the IRB administrators (n = 23) indicated that their boards did grant waivers of parental permission for nonmedical research and treatment (Table 2). In these situations, the research was characterized as involving older

TABLE 1
Characteristics of the Institutional Review Board Review Portfolio of Respondents

Characteristic	*Value*	*Number*	*%*
Approximate number of new protocols reviewed annually ($n = 47$)	1–50	5	11
	51–100	3	6
	101–250	14	30
	251–500	16	34
	>500	9	19
Approximate percentage of protocols that involve children as participants ($n = 49$)	<5%	4	8
	5%–10%	11	22
	10%–25%	21	43
	26%–50%	11	23
	>50%	2	4
Approximate percentage of protocols involving children that involve nonmedical research ($n = 47$)	<5%	7	15
	5%–10%	4	9
	10%–25%	3	6
	26%–50%	6	13
	>50%	27	57

TABLE 2
Comments From Institutional Review Board (IRB) Administrators According to Whether the IRB Ever Grants Parental Permission Waivers

Have Granted Waivers (n = 23)	*Never Grant Waivers (n = 26)*
Consider "degree of risk and degree of interaction."	"Parents [have a] right to know what is being asked of their kids."
Only waived for "very, very, very low risk research involving teens that asks questions about non-controversial matters."	"The high probability that parents would object to researchers contacting their children regarding substance abuse without their knowledge."
Types of research can be waived for "research to be conducted in … normal education practices, … involves the use of educational tests if no identifiers can be linked to kids, … involves the observation of public health behaviors."	"I don't feel there is a good reason for not getting permission of some sort."
Waived when "research would be impossible without [a waiver]."	

Note. Responses to the question, "Does your IRB ever grant waivers for parental permission for non-medical research and treatment?:" Of the 49 respondents, 23 (46.9%) replied "yes" and 26 (53.1%) replied "no."

children, minimal risk, normal educational activities, research dealing with non-sensitive issues, or observational surveys. Among the 26 respondents who indicated that their boards never granted waivers, several (n = 9) reported that their boards had never received a request for a waiver. Among the remainder, the most common reason for not granting parental permission waivers was that the "IRB thinks it is essential" (n = 5) or "parental permission is always required" (n = 3).

The administrators were asked about the most important factor influencing their IRB's decision to grant a waiver of parental permission. The most frequently mentioned factors for granting a waiver were low risk of the research (n = 22), content of the research survey (n = 5), and inability to carry out the survey with parental permission (n = 4). One respondent indicated that the researcher's quality of writing of the application and knowledge of the regulations were important factors.

There was considerable diversity among the IRB administrators who were asked about passive consent, in part due to different interpretations of the term (Table 3). In some instances, the respondent indicated that passive consent was the same as "parental permission waivers"; an "opt-out informed consent" (i.e., no response on the part of the parent was considered an affirmative consent to participate in research); a returned, completed questionnaire without a signature. More than half indicated that they do not allow, or would not consider, passive consent. Among those indicating that their IRB did consider passive consent, 1 respondent noted that, in these situations, investigators were required to inform parents of the research through flyers, mailed information, public service announcements, or

TABLE 3
Perspectives of IRB Administrators by Board Practice of Considering "Passive Consent"

Perspectives of IRB administrators of boards that consider passive consent requests
Passive consent can be considered if the criteria for a waiver of consent are met.
Returning a mail-in survey is considered passive consent.
Passive consent can be considered
In cultures where signing off on a document is not acceptable to potential study volunteers, or
In electronic surveys.
Perspectives of IRB administrators of boards that do not consider passive consent requests
IRBs do not allow either waivers of parental consent or passive consent.
Passive consent is not acceptable under federal regulations: either waive consent or require consent.
This issue has never arisen.

Note. Thirty-six responses to the question, "How does your IRB handle requests for so-called 'passive' consents?:" Of 36 respondents, 11 (31%) replied that their board "will consider these requests" and 22 (61%) replied that their board "does not consider these requests;" 3 (8%) replied that they had never received such a request. IRB = Institutional Review Board.

other media. Only 3 out of 36 indicated that they had never received or discussed such a request.

When asked whether tobacco and substance abuse research involving children was generally considered to involve no more than minimal risk, the administrators were about evenly split between "yes" ($n = 22$) and "no" ($n = 23$); with some equivocal "it depends" ($n = 4$; Table 4). However, the majority of those respondents answering "yes" qualified the type of study by indicating, "yes, if … " the study was anonymous, confidential, did not use audio or video tapes, or was conducted as a survey. Among IRBs willing to consider smoking or substance abuse topics as no more than minimal risk, more than half had granted parental waivers in the past ($n = 12$ out of 22). The IRBs that did not consider these topics as minimal risk were less likely to have ever granted parental waivers ($n = 9$ out of 23). The principal concern of these IRBs was possible punitive actions from the legal system, educational system, or parents.

When making determinations regarding a researcher's request for a waiver of parental permission for research, the IRB administrators were evenly divided on whether their IRB considered state laws regarding a minor's ability to consent to certain types of treatment without parental involvement (23 did consider state laws and 24 did not; Table 5). Among those who did consider state laws, the primary issue was how the state laws affected the adolescent's autonomy. Among those who did not consider state laws, the perspective was that laws affected treatment, not research.

TABLE 4
Perspectives of IRB Administrators of Board Practice in Determining Minimal Risk for Research on Smoking and Substance Abuse

Perspectives of IRB administrators of boards that do consider (some of) these studies to be no more than minimal risk ($n = 22$)
The type and objective of the study is important (e.g., observational, treatment, or counseling).
These issues are regularly discussed by participants in other settings.
Risk is largely dependent on whether findings can be linked to specific participants.
Perspectives of IRB administrators of boards that do not consider these studies to be minimal risk ($n = 23$)
Behavior is illegal; therefore, participant may suffer legal repercussions.
Behavior is not allowed in schools; therefore, participant may suffer reduced educational opportunities.
Behavior is not socially acceptable; therefore, parents may punish adolescents.

Note. Forty-nine responses to the question, "Research with children on topics such as smoking and substance abuse involve no more than minimal risk? (Yes or No)": 30 (45%) replied that their board may consider this type of research to have minimal risk and 23 (46%) replied that their board does not consider this research to be of minimal risk. Also, 4 (8%) replied that "it depends on the specifics of the study." IRB = Institutional Review Board.

TABLE 5
Perspectives of IRB Administrators by Board Practice of Including State Laws in Deliberations

Perspectives of IRB administrators of boards that did consider state laws (n = 23)
State laws affect emancipation status of the minor.
State laws affect rights of minor regarding access to medical care.
State laws affect parental waivers for treatment.
Perspectives of IRB administrators of boards that did not consider state laws (n = 24)
State laws pertain to treatment, not research.
No relevant laws.
Situation has not arisen.

Note. Forty-seven responses to the question: "Does your IRB consider state laws regarding minors' ability to consent for themselves? (Yes or No)": 23 (49%) replied that their board did consider state laws and 24 (51%) replied that their board did not consider state laws. IRB = Institutional Review Board.

The IRB administrators were also asked whether their IRBs required template language (i.e., standard content across all protocols) addressing state and local laws in the informed consent when children are involved in research. Almost two thirds indicated that template language was required. In most cases, the required template language involved issues of child abuse.

Responses by Portfolio Characteristics

Some differences, although not statistically significant, were noted between IRBs with large portfolios (reviewing more than 250 applications per year, n = 25), as compared to those with smaller portfolios (n = 22). IRBs with large portfolios were more likely to grant parental waivers (56% vs. 41% for IRBs with smaller portfolios), less likely to allow passive consent (30% vs. 38%), and more likely to consider smoking or substance abuse topics as generally no more than minimal risk (55% vs. 36%). In a similar fashion, IRBs reviewing a relatively larger percentage of children's protocols (i.e., at least 26% of the portfolio; n = 13) were more likely to waive parental involvement in the consent process when compared with IRBs having no more than 10% of their portfolio involving children (n = 15). Those with a larger percentage of children's protocols were more likely to grant waivers (54% vs. 40%), but were less likely to grant passive consent (29% vs. 40%). There was little difference with regard to whether smoking or substance abuse topics were generally considered to be no more than minimal risk (54% vs. 50%).

Greatest Challenges and Advice to Researchers

Finally, the IRB administrators were asked to provide insight into two general issues: the greatest challenges facing IRBs in the review of research involving chil-

dren and advice to investigators preparing IRB submissions of research involving children. Some of the greatest challenges are shown in Table 6. Several respondents mentioned the issue of coercion of children from parents, peers, or school personnel. For instance, one respondent said, "What may not seem to be a 'big deal' to adults, may adversely affect a child in some way. It's hard to put yourself in their shoes sometimes." Others mentioned the unique concerns associated with special populations, such as mentally or physically disabled children and children in low socioeconomic situations. Weighing benefits and risks is another complicated issue. One respondent underscored problems determining if "the benefit [is] great enough to justify the use of an individual who legally cannot given consent themselves." It is apparent that IRB discussions of child-related research are not simply focused on the child. These discussions must involve a wide range of issues, including the role of school personnel and the need for parents to be informed.

Of particular interest was the advice the respondents gave to investigators preparing IRB applications for research involving children (Table 6). Language of the consent form was clearly a frequent concern, with eight respondents noting either that the child form or parental form required careful attention to language. One respondent suggested, "Have a parent read the protocol before submitting." Two other themes that emerged from the comments were the need for the investigator to (a) understand the ethical issues and legal requirements associated with research, and (b) explain in more detail the practical aspects and procedures that will be used to address the ethical concerns of research involving children. As one administra-

TABLE 6
The Greatest Challenges for IRBs That Arise When Reviewing Research Involving Children and Advice to Researchers Preparing Protocols

Greatest challenges for IRBs
Assuring voluntary, autonomous recruitment of adolescents.
Assuring that benefits outweigh risks.
Reviewing studies of children with mental or physical disabilities.
Getting parental consent in schools with low socioeconomic status.
Appropriately recognizing the concerns of parents without unduly restricting the conduct of important research.
Advice to researchers regarding protocol development
Make language simple, but avoid jargon.
Consider standards and mores of parents.
Understand the legal requirements (federal, state, and local) and ethical concerns of research involving no direct benefit to children
Be able to show that the research is truly necessary.
Let the IRB know how the children will be told about the research and how the investigator will ensure that the child's assent is honored.
Consider the fact that research with children of certain ethnic groups, such as Native Americans, may involve another level of scrutiny.

Note. $N = 49$. IRB = Institutional Review Board.

tor said, "Skip the hidden agendas and be up front and complete with the IRB about your intentions and the practical aspects of conducting the research."

DISCUSSION

The purpose of this study was to understand factors important to IRBs in the consideration of pediatric and adolescent research. The intent was to solicit information from a broad range of IRBs, not restricted to IRBs who regularly review a large number of such studies. The IRB administrators responding to this questionnaire did represent IRBs that reviewed protocols involving children, including nonmedical protocols, on a regular basis. However, protocols involving children were not the majority of their portfolios. The responses of these administrators were divergent. For instance, about half of the respondents indicated that they would never grant waivers of parental permission, whereas about a third indicated that they would consider passive consent protocols. This finding is similar to the Mammel and Kaplan (1995) survey in which 69% of IRB administrators indicated that *all* research on minors required parental permission. In both studies, there are substantial differences of opinion among IRBs regarding waivers. There was some indication, although not significant, that IRBs with larger portfolios or having a higher percentage of children protocols were more likely to grant parental permission waivers. With increased experience, IRBs may be more comfortable interpreting the federal regulations with greater flexibility.

Determination of risk was the most frequently cited important factor for discussions of waivers of parental permission. IRBs willing to consider smoking or substance abuse topics as minimal risk were more likely to consider granting waivers. Risk was also thought to be an important factor in the Mammel and Kaplan (1995) study. Minimal risk research in which the participants are "mature minors" was cited by the National Commission for Protection of Human Subjects of Biomedical and Behavioral Research as one of three situations[1] in which a modification or waiver of the parental permission requirement may apply (Weddle & Kokotailo, 2002).

Professional organizations recommend that researchers encourage parental involvement in adolescent health care (Committee on Bioethics of the American Academy of Pediatrics, 1995; Council on Scientific Affairs of the American Medical Association, 1993; Society for Adolescent Medicine, 1997). The role of par-

[1]The Federal Policy for the Protection of Human Subjects (2001) cited neglected or abused children as a participant population for which parental permission may be waived. The other two situations cited by the National Commission (1977) were (a) research related to the incidence or treatment of certain conditions in adolescents for which they legally may receive treatment without parental permission and (b) research involving children whose parents are legally or functionally incompetent.

ents in nonmedical research is less clear. Federal regulations (Federal Policy, 2001) and policies note the importance of reviewing the need for parental permission but do not require consent in all research (NIH, 1998).

According to Subpart D, the right for minors to consent independently to treatment research can be linked to the right to consent to treatment (Federal Policy, 2001; Weddle & Kokotailo, 2002). Consequently, because most child-based issues are determined at the state level, state laws pertaining to the ability of the minor to consent for treatment are relevant to the discussions of consent for treatment research. However, the independence of that decision is a special concern for research involving substance abuse and children (Brody & Waldron, 2000). Possession, use, and purchase of illicit drugs, alcohol, and tobacco are illegal activities among children and adolescents. Hence, adolescents tend to be more covert with these problem behaviors. Referral to treatment research programs often occurs in response to detection by parents, schools, or the criminal justice system. In these situations, IRBs and investigators need to pay special attention to the voluntary provision for informed consent. Providing an annotated list of relevant laws as part of the IRB's application information can strengthen awareness and knowledge of state laws among researchers and IRB members.

In research involving adolescents, investigators should, at a minimum, inform the adolescent and obtain assent. However, because the adolescent is establishing autonomy from the parent, the adolescent does not look on the distinction of assent as a lesser role in the informed consent process favorably. One IRB administrator summarized the issue:

> Teens do not take well to being treated like children. The issue of assent and permission confuses many people. When used with adolescents, I think that it misses the mark. That is, the minor should be treated as an autonomous decision-maker just as if they were [an] adult.

About half of the respondents indicated that the IRBs considered nonmedical research on smoking and substance abuse among teens to be generally no more than minimal risk. However, these respondents answering affirmatively also qualified their definition of research. Consequently, although simple yes–no responses appear to be split, the general consensus of the respondents was that there were risks for the minor participants in these types of research, largely because the behaviors often involve illegal activities.

The responses to the question regarding the role of state laws in the discussions about a minor's ability to consent were also evenly divided. The responses may reflect differences in the state laws or differences of interpretation by IRBs. Some administrators indicated that state laws pertained to treatment, but not to research.

Challenges for the IRBs when considering these protocols focused on language in consent forms, both for adult and adolescent consent forms. The issue is not sim-

ply the text educational level, but also the choice of words (Ford et al., 2001). Ford et al. conducted interviews with high school students about their interpretations of a statement explaining protection and limitations of confidentiality in a hypothetical clinic study. They concluded that references to legal requirements made teens wary. Although adolescents know far less than adults about the protections of confidentiality, they are far more likely to be concerned with breaches of privacy. Hence, Ford et al. recommended careful word selection and behavior by the researcher to convey trustworthiness. This study of IRB administrators supports that recommendation. One respondent noted:

> Writing a good, understandable assent (let alone a comprehensible parental permission) is an art. Researchers invariably over-estimate their population's understanding of terms—like "focus groups," "key informants," "consent," [and] "instrument"—and under-estimate the degree of control families wish to have over their (adult's and child's) private information.

This study is limited by the low response rate to the survey. Although the survey was sent to a representative sample of IRB administrators, how generalizable respondents' answers are is unclear. Somewhat reassuring are similarities between information reported on this survey and other surveys of IRB practices. For example, an examination of 47 IRB Web sites conducted by the IOM in 2003 found that none of the sites provided guidance on minimal risk research beyond the common rule, and that 64% provided template language for informed consent (National Research Council, 2003).

The findings of this study support recent IOM recommendations regarding ethical conduct of research involving children (Field & Behrman, 2004). The report recommendations highlight the role of the IRB as an educator for researchers regarding the range of possibilities for the informed consent process. The federal regulations are viewed as outlining important aspects of the informed consent process to assure that potential participants can make appropriate, fully informed decisions rather than being viewed as a set of restrictions. IRBs can help investigators by regularly providing training sessions that focus on alternative procedures to conduct informed consent. Identifying alternative procedures is not an attempt to circumvent regulations. Rather, just as the informed consent process is a dialogue between the investigator and potential participant so an informed decision can be made, the IRB training should be a dialogue that enables a range of important research to be conducted in an ethically appropriate manner.

The IRB not only has the responsibility to determine that certain conditions for protecting participants are met, it also has the freedom to utilize the flexibility of the regulations to ensure that participants being asked to participate in a particular protocol have appropriate and adequate protections. The IOM recommendations include guidance on granting waivers of parental permission for adolescent partic-

ipation in research that is consistent with the practices reported in this study (Field & Behrman, 2004, p. S-16). As researchers and IRBs work together, they often find creative solutions to challenges that arise in the course of planning and carrying out research. By working together, it is possible to identify solutions that are consistent with regulatory and ethical requirements, that preserve research design and integrity, and that ensure the protection of research participants.

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