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Human Participants Challenges in Youth Tobacco Cessation Research: Researchers' Perspectives

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Recruiting adolescents into smoking cessation studies is challenging, particularly given institutional review board (IRB) requirements for research conducted with adolescents. This article provides a brief review of the federal regulations that apply to research conducted with adolescents, and describes researchers' experiences of seeking IRB approval for youth cessation research. Twenty-one researchers provided information. The most frequently reported difficulty involved obtaining parental consent. Solutions to commonly reported problems with obtaining IRB approval are also identified. Waivers of parental consent can facilitate recruitment of youths into studies; however, researchers must ensure that their protocols comply with federal regulations when requesting a waiver.

Keywords: consent, ethics, IRB, human participants, smoking

The prevalence of adolescent smoking remains unacceptably high. In 2002, 17.7% of 10th graders and 26.7% of 12th graders reported having smoked in the last month; 16.9% of 12th graders smoke on a daily basis (Johnston, O'Malley, & Bachman, 2003). Although the majority of adolescent smokers express a desire to quit smoking, quit rates among youths have been fairly low (U.S. Department of Health and Human Services [USDHHS], 1994; Zhu, Sun, Billings, Choi, & Malarcher, 1999). Without appropriate early intervention, most adolescent smokers can be expected to continue smoking throughout their adult years.

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The evidence base regarding effective tobacco cessation interventions for youths is small, and experts in the field report that "critical knowledge gaps" remain in many aspects of youth tobacco use and cessation (Winickoff et al., 2003). The Youth Tobacco Cessation Collaborative was unable to identify best practices for youth cessation because of limited data; they concluded that although promising approaches exist, rigorous science is required to ensure that effective programs are developed and disseminated (McDonald, Colwell, Backinger, Husten, & Maule, 2003). An added challenge for researchers is the frequently reported difficulty of recruiting adolescent participants into cessation studies. Researchers report that recruitment difficulties often stem from institutional review board (IRB) requirements for research conducted with adolescents, specifically involving issues of parental consent and confidentiality of adolescent reports to research staff (Backinger et al., 2003; McCormick et al., 1999; USDHHS, 1994).

Because participation in a smoking cessation intervention indicates to parents that their son or daughter is smoking enough to qualify for such a program, obtaining parental consent requires researchers to share sensitive information (e.g., smoking status) of research participants. As a result, many teens inform research staff that they do not want to participate in the intervention research if their parents must provide consent. Written parental consent results in study samples that are not representative of the population of interest with fewer minorities, less experienced cigarette smokers, and fewer high-risk adolescents, as compared to an implied or "passive" consent procedure (Dent et al., 1993).[1] Waivers of parental consent can facilitate greater recruitment of youths into studies; however, researchers need to be aware of the federal regulations and ensure that special considerations are included in the research protocol when requesting a waiver from their IRB.

This article provides a brief review of the federal regulations that apply to research conducted with adolescents, and it describes researchers' experiences of seeking IRB approval for youth smoking cessation research protocols. The focus is on identifying both the barriers and innovative solutions to IRB challenges. Solutions to commonly reported problems will allow scientifically rigorous research to move the field of adolescent smoking cessation forward, establishing a sound evidence base for best practices in youth smoking. The issues raised in this article likely apply to other areas of research involving adolescent participants, including adolescent substance use and treatment, a variety of mental health conditions, and sexual behavior.

FEDERAL REGULATIONS RELEVANT TO ADOLESCENT RESEARCH

In the past 6 years a number of institutions, including several prestigious universities with substantial federally funded research programs, were temporarily sus-

[1]Implied consent typically involves providing the parents with specific details about the protocol in advance; unless parents actively object to their child's involvement, they are assumed to give consent.

pended from conducting human research by the federal office whose responsibility includes monitoring research activity with human participants ("A Higher Standard," 1999; Begley, 2002; Landers, 2001). In response, IRBs across the country began tightening up their review requirements to avoid similar suspensions. Research conducted with "special" or "vulnerable" populations, which includes adolescents, has been particularly affected by this shift.

The Federal Policy for the Protection of Human Subjects, Subpart D (2001; USDHHS, 2001) describes the required protection of children (anyone under the age of 18) involved as participants in research studies. Subpart D largely focuses on issues surrounding parental permission. According to the regulations, both parental permission and adolescent assent (the minor's agreement to participate) *must* be obtained before a minor can serve as a research participant. The regulations also specify circumstances in which the requirement for parental permission may be waived. IRBs may waive this requirement when (a) the research involves no more than minimal risk, (b) the waiver of parental permission will not adversely affect the welfare of research participants, and (c) the research project could not be practically carried out without the waiver of parental permission. It is important to note that the terminology of *passive* or *implied* consent is not utilized in the federal regulations; when researchers request to use an implied consent procedure, they are actually requesting a waiver of parental permission and must meet all three criteria outlined in Subpart D.

In addition to the federal regulations, there have been other important reports with recommendations for investigators conducting research with children. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1977) detailed additional circumstances where alternative protective mechanisms might be utilized in place of a required parental permission component. For example, in some states adolescents can legally receive treatment for a variety of medical and psychological conditions (e.g., substance abuse) without parental knowledge or permission. Therefore, adolescents should also have the opportunity to make their own decisions about participating in research relating to the treatment of these conditions. A recently released Institute of Medicine (IOM) report (Field & Behrman, 2004) recommended that IRBs consider waivers of parental permission for adolescent participants when "the research is important to the health and well-being of adolescents" (p. 19), when it cannot reasonably be conducted without the waiver, or when it involves treatment the adolescent can consent to receive under state laws. In addition to these factors, the investigator should present evidence that the adolescents are capable of understanding the research project and their rights as a participant, and show that the protocol contains safeguards to protect the adolescent from research risks. In addition to the issue of waivers of parental consent, the IOM report reviews the federal regulations surrounding research with children and provides thoughtful, detailed recommendations for investigators, IRBs, and governmental and research organizations (Field & Behrman, 2004).

METHOD

To further investigate the difficulties of conducting teen smoking cessation research given IRB interpretations of the federal regulations, tobacco researchers shared detailed information regarding their teen cessation interventions and their experiences in obtaining IRB approval.

The information used to write this article was collected from the experiences of researchers who have engaged in smoking cessation research with youths. A direct query was posted to the Society for Research on Nicotine and Tobacco (SRNT) listserv. SRNT is a professional organization to which many researchers conducting smoking cessation research belong. In addition, specific requests to share "lessons learned" were sent to 12 funded investigators of ongoing cessation trials. These investigators were identified by the program director for youth tobacco research in the Tobacco Control Research Branch of the National Cancer Institute. Researchers with experience in the area of youth smoking behavior constructed the questions of interest. These questions were e-mailed to researchers, and responses were returned via e-mail or phone.[2]

Researchers who responded provided information about their professional affiliation and their experience serving on IRB committees. In addition, researchers provided specific details about the cessation program being evaluated or studied (e.g., setting, format, type of treatment, age range targeted, etc.). Several questions were asked concerning the IRB requirement of parental consent (e.g., Did researcher request a waiver of parental permission?, Did the IRB have concerns?, Was a waiver granted?, etc.). Additional questions included the following: Was the IRB approval for evaluation only or did it also include the intervention activities? Were researchers required to inform parents that their teen was seeking assistance in smoking cessation? Did the IRB express concerns about protecting teens' confidentiality? Were there any complaints or unexpected problems reported to you? What IRB barriers most concern you? What are your most successful solutions?

Participants

Table 1 displays characteristics of the smoking cessation researchers who provided information for this article. Twenty-one researchers responded to the questions: 16 from the SRNT listserv and 5 from direct queries to funded researchers. The researchers who provided information for this article represent approximately 20% of the investigators who received funding for youth smoking cessation in fiscal years 2000 through 2002 (Backinger et al., 2003). Most of these individuals described their professional affiliation as a university or academic setting (n = 18).

[2]A complete list of questions can be obtained from Kathleen R. Diviak.

TABLE 1
Smoking Cessation Researcher Characteristics

Variables	*n*	*%*
Source		
SRNT listserv	16	76%
Direct query	5	24%
Work setting		
University or academic	18	86%
Hospital or medical center	8	38%
Independent research	1	5%
Public health department	1	5%
Ever served on IRB?		
No	15	71%
Yes	6	29%

Note. $N = 21$. SRNT = Society for Research on Nicotine and Tobacco. IRB = Institutional Review Board.

The remaining respondents were employed in hospitals or medical centers (most were teaching institutions), independent research settings, or the state department of public health. Six of the 21 researchers who provided information reported that they have served on an IRB committee at some point in their careers.

SMOKING CESSATION INTERVENTION CHARACTERISTICS

The youth cessation interventions being studied by these researchers were diverse in their characteristics. Some programs were offered in multiple settings. The settings of the interventions were varied and included the following: medical clinics ($n = 7$), schools ($n = 9$), community organizations ($n = 4$), and other settings ($n = 3$; e.g., adolescent substance abuse clinic, Internet-based interventions, self-help interventions, etc.). Approximately half of the programs were presented to teens in a group format, and half were individual treatment programs. The age range targeted by these programs tended to be high school-age adolescents ranging from 13 to 18 years old; however, two programs targeted adolescents as young as 11 to 12 years old.

The treatment characteristics of these programs covered a complete range of smoking cessation intervention components. The most common intervention component involved in-person behavioral counseling (13 programs). Six programs involved pharmacological treatments such as nicotine replacement or use of the prescription medication *buproprion* for smoking cessation. Three of the programs involved physician advice, 8 involved phone counseling, 4 included Internet-based

treatments, 8 used self-help manuals, and 3 utilized other components (e.g., CD-ROM, tailored cessation materials, monetary incentives for low carbon monoxide levels).

PARENTAL CONSENT FOR PARTICIPATION

The most frequently reported difficulty in the IRB approval process involved issues surrounding parental permission for teen participation in the research study. Of the 21 researchers, 13 (62%) sought a waiver of parental permission from their IRB. The rationale used for justifying a waiver in their IRB applications typically was that (a) teen participation in this study involves minimal risk; (b) if parental permission were required it would be difficult to recruit teens into the study; (c) those teens who feel comfortable asking their parents for permission would not be representative of teen smokers, thus biasing the sample; and (d) a need to maintain the confidentiality of teens' responses (in particular their smoking status) from parents and school administrators. Two researchers seeking a waiver referenced state laws that adolescents over a certain age have the right to medical or dental treatment and chemical dependency treatment without parental permission. Eight of the 13 researchers who requested a waiver received approval from their IRB to waive written parental permission (see Figure 1). Four of these researchers collected teen assent only. Three researchers were given permission to waive written permission, but were required to obtain verbal parental consent from any adolescent participating in the study. Researchers were often required to get a "script" approved for the parental permission process and document the procedure by keeping detailed call logs and phone bills. Although this strategy decreased problems often associated with adolescents delivering permission forms to their parents and

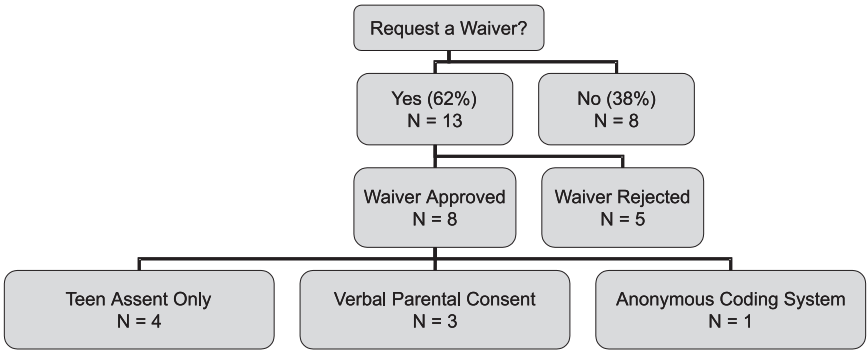

FIGURE 1 Outcomes of researcher request for a waiver of parental consent from the institutional review board

then returning to research staff, it did not alleviate recruitment problems stemming from adolescents wanting to keep their smoking status private from their parents. The final project to receive a waiver of parental permission utilized an anonymous coding system and teen assent. The anonymous coding system was used to prevent any matching of teen participant with their questionnaire data; consequently, this system prohibited any follow-up data from being collected.

MULTIPLE IRB APPROVAL

Three researchers were required to seek approval from multiple IRBs, as their studies were being conducted at several locations. Two of these were cessation programs operating in school settings that were required to obtain approval by the IRB at each school in addition to their own university IRB. At a minimum, this resulted in increased administrative work in submitting multiple applications, tracking their progress, and responding to the specific issues that arose from each board. Moreover, as the number of IRB applications increased, so did the potential for additional problems. For example, one investigator was required to obtain IRB approval from multiple health clinics that served as research sites. The IRB at one health clinic required "in-person" parental permission, which required research staff to obtain written permission by going to the parents' homes and workplaces. The researcher reported that parents were generally not amenable to this and that recruitment efforts at that particular site failed. This was the sole report we received of an IRB requiring in-person written parental permission for teens to participate in the research project.

PROGRAM EVALUATION ONLY

Researchers can seek IRB approval for providing a smoking cessation intervention, for the study or evaluation of the intervention, or both. Three of the researchers who provided information sought IRB approval for treatment evaluation only (not the intervention itself, which would be offered to teens whether they participated in the evaluation of that treatment or not). Of these three studies, 2 received waivers of parental permission. Ten researchers reported seeking approval for both the smoking cessation intervention and the evaluation of the intervention. Of these, 6 sought waivers of parental permission. Only 2 received approval to enroll participants without written parental permission. One researcher was allowed to collect verbal parental permission, another utilized an anonymous coding system. It might be easier to justify a waiver of parental permission in cases where the researcher is only collecting questionnaire data to evaluate the efficacy of the intervention.

IRB CONCERNS ABOUT PARENTAL PERMISSION WAIVERS

IRBs may vary in their propensity to grant waivers of parental permission. We asked researchers if they thought it was likely their IRB would grant a request for a waiver in youth tobacco cessation intervention research. There was no consistent response. Three researchers responded that their IRB would never grant a waiver of parental permission; three answered that their IRB would be likely to waive parental consent; four responded that their IRB might grant such a request, but that it was likely to be a rare occurrence; and the remaining respondents were unsure or did not answer.

According to the researchers, IRBs often had concerns when approached with a protocol requesting a waiver of parental permission. Often, the IRB concern centers around whether participation in the research protocol involves minimal risk (the following are quotes from researchers, not IRB members):

- "Although [participating in the study is] low-risk, teens are viewed as a vulnerable population, and just participating in a survey could adversely affect some individuals."
- "[The IRB] grills us but, if the intervention and measures meet some standards of 'benignness' they appear willing to approve passive consent."
- "[To deal with IRB concerns with waiving parental consent we had] many meetings with IRB … finally anonymity of the kids worked … . Unfortunately there can be no follow-up."

Other IRB concerns with a request for a waiver center around the need to show that requiring parental consent will adversely affect the research protocol in a significant manner. For example,

- "The IRB wanted us to see if it would be a problem to recruit and if it was we could ask for a waiver. We did have a problem … . So they waived the requirement for 16 and 17 year old teens."
- "[The IRB] requires evidence that failure to use passive consent or waiver would influence the validity/utility of study findings."

Other IRB concerns centered on the concern parents may have when their child is recruited to participate in a research study:

- "[The IRB was] concerned about … preventing a situation in which a parent complained that their child was participating in a research study without their knowledge."

- "[The IRB] will not approve protocols without parental consent, but may allow verbal parental consent."

Some researchers felt the IRB concern was based on risk aversion rather than the nature of the protocol (e.g., minimal risk, welfare of participants adequately protected, etc.).

COMPLAINTS AND ADVERSE EVENTS

Three researchers reported that they had received complaints about their research study. The first researcher reported that 5 parents (out of 2,000) complained that parents should not have received a recruitment phone call from research staff without first having their consent to be called. A second researcher stated that 2 parents were unhappy that researchers were able to access addresses to send teens recruitment letters. It is interesting that both of these complaints involved study actions that took place during recruitment and prior to collecting informed consent and enrollment in the study. The final complaint reported was that some participants requested to be dropped from the study because they no longer wished to receive counseling or follow-up calls from the research team. No other researchers reported a complaint about participation after the teen was enrolled in the study. Notably, none of the studies that received a full waiver of parental consent reported complaints. Three studies, all involving pharmacological treatment for smoking cessation, reported adverse events on the part of teen participants. However, none of the reported adverse events was severe or prompted any change in protocol from the researchers or their IRBs.

RESEARCHERS' SOLUTIONS FOR IRB ISSUES

All the researchers were asked to describe their solutions or responses to IRB concerns. The strategies used fell into four general categories: making the parental permission process easier, preserving the confidentiality of adolescents' smoking statuses, obtaining a waiver of parental permission, and improving the entire IRB application process.

Easing the Parental Permission Process

Some researchers felt that obtaining a waiver of parental permission would not be an option, and researchers developed other methods of improving the recruitment process. Collecting verbal permission from parents rather than asking teens to carry home a consent form, get their parents signature, and then return it to study

staff may improve recruitment rates. Some teens forget or lose parental permission forms, and some parents do not take the time to read and sign the form even if they are not opposed to their teen participating in the study. How does verbal permission work in practice? Research staff secure the teenager's permission to call their parents. Research staff then use a script to describe the study, secure parents' verbal permission to allow their teen to participate, log the call in permanent study records, and keep a copy of the phone bill. However, this is not a solution for those teens who will not participate in a study because they do not want their parents to know that they smoke.

Protecting Confidentiality of Adolescents' Smoking Status

Some researchers have altered the content and focus of their smoking cessation interventions. These individuals developed programs that could be described as both "tobacco prevention and cessation" programs or "tobacco education" so that their intervention could target and enroll nonsmoking as well as smoking teens. As a result, participation in the study would not imply that the teenager has had any experience with tobacco. In the parental consent documents, researchers directly state that this study is recruiting and enrolling teens who have never smoked, those who have tried smoking, and those who are regular smokers. Some researchers report that teens are more willing to approach their parents for permission to enroll under these conditions. However, there is a cost to this type of strategy. Adding prevention programming beneficial to those teens who have never smoked may weaken an otherwise strong cessation program, particularly if including prevention modules takes time from teaching cessation skills and strategies to teens who are regular smokers.

Another solution utilized by tobacco researchers involves consenting a whole school or entire class to participate in the intervention prior to identifying or recruiting eligible teens. What would this look like in practice? At the beginning of the school year, researchers send parents of all students in the school or class letters with detailed information about the smoking cessation program offered at the school. Parents are told the conditions under which students would be eligible to participate (e.g., student expresses interest in quitting) but that the school will not notify parents if their child participates in the intervention. Parents are then given the opportunity to decline their child's participation. If parents do not want their child to participate, they can complete a form to notify the school; otherwise, their child, if they provide assent, will be allowed to participate. This strategy is typically referred to as an "implicit" or "passive" permission procedure; it is important to note that it can be used only with a waiver of parental permission.

Seeking Waiver of Parental Permission

Other researchers have focused on making a compelling case for a waiver of the parental permission requirement. Two researchers who received a waiver of parental permission referenced state statutes or laws on the age an adolescent can consent on their own to participate in medical treatment or treatment for substance use. Most of the researchers who shared their experiences for this article were unaware of any relevant laws in this area. The laws regulating the ability of minors to consent to medical treatment vary by state and by the specific medical or psychological condition in question. It may be well worth the effort to research local statutes and laws, as this information may serve as an additional point of information for IRB members who are evaluating research protocols with waiver requests. Emphasizing that informing parents that their child smokes through the permission form is a violation of the adolescent's confidentiality may also bolster an argument for a waiver of parental permission.

If researchers are requesting a waiver of parental permission, special attention should be paid to protecting the welfare of the adolescent participants as required by the federal regulations. There are many different ways to do this depending on the nature of the intervention and the participant characteristics. For example, some interventions may choose to involve a nurse or other responsible adult not directly related to the research project who can explain the purpose and nature of research to the minor and ensure that the adolescent understands and agrees to participate in the study (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1977; Rogers, Schwartz, Weissman, & English, 1999). One innovative suggestion that may satisfy IRBs is to involve the community in the development of the research protocol, which would provide an assurance that the protective measures put in place match the community standards (Mammel & Kaplan, 1995). The IOM report (Field & Behrman, 2004) stated that investigators seeking a waiver should be able to demonstrate that their adolescent participants are capable of understanding the research and their rights as a participant. Finally, including a clear and detailed plan in the IRB application for any of the alternate protective mechanisms described earlier may also indicate to IRB members that the welfare of adolescent participant is being adequately considered by the investigators.

Another solution that has been successfully used by some researchers is to seek IRB approval for program evaluation only and not the smoking cessation intervention. IRBs may be more likely to waive parental permission if the study involves only completing questionnaires. Researchers who have used this technique argue in their IRB application that the teen will be participating in the smoking cessation intervention as part of routine programming in their school or medical clinic independent of the research study. These researchers argue that they are asking teens to

complete surveys only to evaluate effectiveness of the intervention. This strategy emphasizes the minimal risk involved in completing questionnaires that are kept confidential.

Another strategy reported by the researchers has been to collect anonymous data; however, there is a significant scientific cost to this strategy. Anonymous data prohibits anything other than an immediate follow up. Given the nature of addictive behavior and the high relapse rates seen in studies of adults who have been participating in smoking cessation programs, the information to be gained from immediate follow up is significantly limited and compromises the scientific rigor of a study.

Improving the Application Process

The most frequently reported solution to IRB concerns was to be persistent in efforts to secure approval for the study, learn to work collaboratively with (rather than fight against) the IRB, and engage in frequent communication to adequately understand and address concerns. In addition, researchers who obtained waivers of parental permission reported frequent contact with their IRBs prior to submitting the initial application and during the application process to understand concerns and address them completely and quickly. Some researchers reported that after an initial hesitation to approve a waiver of parental permission, IRBs were responsive to the needs of researchers when engaged in a dialogue that clarified the researchers' needs and concerns. For example, one researcher reported that the IRB refused to grant a waiver of parental permission, but instructed the research team to document any recruitment problems and contact the IRB with a new request for a waiver using the data to justify the request. Eventually, the IRB approved a waiver of parental permission for teens 16 and older (the study participants ranged in age from 13–17). In addition, some researchers commented that many universities have developed very clear guidelines with regard to writing IRB applications and consent forms and that following these guidelines minimizes problems with receiving approval.

LIMITING FACTORS

There are many factors that influence the IRB approval process for researchers who engage in smoking cessation intervention with minors. Pharmacological interventions with teens will likely require parental permission. Although some IRBs may allow verbal parental consent in these studies if it is well-documented, this is not the solution to adolescents not wanting their parents informed of their smoking behavior. Some states have laws or statutes that may influence an IRB's decision making. For example, some states require any research study being con-

ducted in a school to secure written parental permission before students can participate, without any exceptions. There are also significant IRB variations. What one IRB is willing to grant, another will never allow (Field & Behrman, 2004; Mammel & Kaplan, 1995; Rogers et al., 1999). Researchers must know their IRB and tailor their application to the preferences and leanings of their particular board. It is worth trying to learn as much as possible about the preferences and decision-making styles of the IRB prior to submitting the application.

SUMMARY

The general public wants appropriate oversight and safeguards in place in research studies, but they also view health research as having great potential value and generally want more access to randomized controlled clinical trials (Levine, 1995). Although adolescents are a "special" or "vulnerable" population, they should not be overlooked by researchers; they also have the right to benefit from research that can improve their health and well-being (Mammel & Kaplan, 1995). Recommended smoking cessation interventions for adolescents to date are based on expert opinion alone or programs that appear promising (McDonald et al., 2003; Winickoff et al., 2003). The knowledge gaps in the field can be bridged only with quality science. Ensuring that adequate numbers of smoking teens representative of the population enroll in these studies will likely require waivers of parental permission in many of the intervention studies. Allowing this research to move ahead while ensuring that appropriate safeguards are in place will require increased communication and collaboration between smoking researchers, research ethicists, and IRB members.

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REFERENCES

Backinger, C. L., McDonald, P., Ossip-Klein, D. J., Colby, S. M., Maule, C. O., Fagan, P., et al. (2003). Improving the future of youth smoking cessation. *American Journal of Health Behavior, 27*(Suppl. 2), S170–S184.

Begley, S. (2002, November 1). Review boards pose threat to social scientists' work. *Wall Street Journal,* p. B1.

Dent, C. W., Galaif, J., Sussman, S., Stacy, A., Burtun, D., & Flay, B.R. (1993). Demographic, psychosocial, and behavioral differences in samples of actively and passively consented adolescents. *Addictive Behaviors, 18,* 51–56.

Federal Policy for the Protection of Human Subjects, 45 C.F.R. § 46 (2001). Retrieved November 9, 2004, from http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm

Field, M. J., & Behrman R. E. (Eds.). (2004). *The ethical conduct of clinical research involving children.* Washington, DC: National Academy Press.

A higher standard for human research [Editorial]. (1999, June). *Nature, 5,* 591.

Johnston, L. D., O'Malley, P. M., & Bachman, J. G. (2003, December). *Teen smoking continues to decline in 2003, but declines are slowing.* Retrieved February 9, 2004, from University of Michigan News and Information Services Web site: http://www.monitoringthefuture.org

Landers, S. J. (2001). *Problems prompt closer scrutiny of human research.* Retrieved November 9, 2004, from http://www.amednews.com/2001/hlsb1119.htm

Levine, R. J. (1995). Adolescents as research subjects without permission of their parents or guardians: Ethical considerations. *Journal of Adolescent Health, 17,* 287–297.

Mammel, K. A., & Kaplan, D. W. (1995). Research consent by adolescent minors and institutional review boards. *Journal of Adolescent Health, 17,* 323–330.

McCormick, L. K., Crawford, M., Anderson, R. H., Gittelsohn, J., Kingsley, B., & Upson, D. (1999). Recruiting adolescents into qualitative tobacco research studies: Experiences and lessons learned. *Journal of School Health, 69,* 95–99.

McDonald, P., Colwell, B., Backinger, C. L., Husten, C., & Maule, C. O. (2003). Better practices for youth tobacco cessation: Evidence of review panel. *American Journal of Health Behavior, 27*(Suppl. 2), S144–S158.

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. (1977). *Report and recommendations: Research involving children* (DHEW Publication Nos. [OS] 78-0013 and [OS] 78-0014). Washington, DC: U.S. Government Printing Office.

Rogers, A. S., Schwartz, D. F., Weissman, G., & English, A. (1999). A case study in adolescent participation in clinical research: Eleven clinical sites, one common protocol and eleven IRBs. *IRB: A Review of Human Subjects Research, 21,* 6–12.

U.S. Department of Health and Human Services. (1994). *Preventing tobacco use among young people: A report of the Surgeon General* (DHHS Publication No. 017–001–00491–0). Atlanta, Ga: Author.

U.S. Department of Health and Human Services. (2001). *Protections for children in research: A report to congress in accord with Section 1003 of P.L. 106–310, Children's Health Act of 2000.* Retrieved November 9, 2004, from http://www.hhs.gov/ohrp/reports/ohrp502.pdf

Winickoff, J. P., Pbert, L., Klein, J. D., Lando, H. A., Carroll, B. C., Mermelstein, R., et al. (2003). Youth tobacco control research and activities in the United States: The current national landscape. *Nicotine & Tobacco Research, 5,* 435–454.

Zhu, S. H., Sun, J., Billings, S. C., Choi, W. S., & Malarcher, A. (1999). Predictors of smoking cessation in US adolescents. *American Journal of Preventive Medicine, 16,* 202–207.