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This study provides new information on how passive and active consent methods work in practice. Based on results from two junior high schools, we found that (1) almost all parents received consent packages sent by regular first-class mail, but getting them to pay attention to the materials often required additional communication methods, (2) nonresponse to passive consent typically reflected conscious parental approval, (3) nonresponse to active consent generally signified latent consent, not a deliberate refusal, and (4) vigorous retrieval methods substantially raised active consent response rates, but at a high cost in time and money. These findings suggest that passive consent can provide a viable alternative to active consent when supplemented by appropriate backup and privacy safeguard measures.

AN ASSESSMENT OF ACTIVE VERSUS PASSIVE METHODS FOR OBTAINING PARENTAL CONSENT

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This article discusses the results of a pilot study assessing the effectiveness and costs of two methods for obtaining parental approval to conduct research with minors: active versus passive consent. The first method (active consent) involves asking all parents to return a signed consent form to indicate whether they do or do not want their child to participate in the research activities. Under active consent procedures, parents who fail to return a permission slip, as well as those individuals who indicate on the form that they do not want their child to participate in the research are treated as "parental refusals." The second

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procedure (passive consent) asks parents to return a form only if they do not want their child to participate. If parents do not refuse, they are assumed to have granted permission for their child to participate in the research.

Researchers who have used active consent report that it yields unacceptably low response rates of only 50-60% and underrepresentation of important groups—Blacks, Asian Americans, low achievers, children with less well-educated parents, and those at risk for engaging in problem behavior (Kearney et al., 1983; Josephson and Rosen, 1978; Lueptow et al., 1977; Severson and Ary, 1983; Thompson, 1984). Such results limit the scientific validity and generalizability of survey research conducted with children; when the research includes an experimental design aimed at evaluating school-based drug prevention programs, the problems are compounded. Substantially reduced sample sizes can make it difficult to detect all but the most powerful treatment effects, and unequal distribution of specific groups across experimental conditions can produce false positive or negative effects (Biglan and Ary, 1985).

Because of its potential for severely reducing sample size and increasing sample bias, many researchers have replaced active with passive consent methods (Biglan et al., 1987; Murray et al., 1987). However, thoughtful observers disagree about whether passive consent procedures adequately fulfill requirements for obtaining informed parental consent. Some researchers argue that passive consent does not fully inform parents about the research or give them sufficient opportunity to refuse participation. Others question the underlying assumption that parents who fail to send in a refusal form have received the notice and consciously decided that their child should participate in the research. They interpret the bias toward nonresponse in "at-risk" groups as reflecting parental concerns that these children are more likely to be jeopardized by the research, particularly if confidentiality safeguards against disclosure of sensitive information are not adequately enforced.

In contrast, critics of active consent believe it requires overly stringent informed consent procedures, especially when applied to programs that offer substantial benefits, implement rigorous data safeguards, and pose minimal risk to students. They argue that carefully designed passive consent methods can avoid the negative consequences of active consent while ensuring that parents receive the consent materials, pay attention to them, and have sufficient time to refuse participation. They also believe that failure to return a signed active consent form is more likely to reflect apathy or inertia than objection to the research.

To date, however, the debate has been carried on in the absence of evidence about the meaning of parental nonresponse under either method, the effectiveness of passive consent at informing parents about the research, or the potential for raising response rates by vigorously pursuing active consent. Based on experience in two junior high schools, this study addresses those issues.

STUDY QUESTIONS AND BACKGROUND

Undertaken before launching a multiyear smoking and drug prevention experiment in 30 West Coast schools, the pilot test sought information about the following questions: (1) Can active consent response rates be substantially increased by implementing rigorous retrieval methods? At what cost? (2) Is parental nonresponse to active consent more likely to indicate apathy or a deliberate refusal? (3) Does parental nonresponse to passive consent indicate a deliberate decision to permit the child to participate in the research? (4) How effective is regular first-class mail at informing parents? The data were collected in response to a request from Rand's Human Subjects Protection Committee (HSPC), which would then use the results to inform its deliberations about approving active or passive consent for the large-scale project.

In addition to providing consent data, the pilot test was the primary vehicle for learning how well the curriculum and data collection procedures worked before implementing them in the 30 experimental schools (Ellickson, 1984a, 1984b). Hence, rather than match the two pilot schools on key population characteristics, we selected schools that would best represent the range of experience and backgrounds that the main study's survey respondents were likely to demonstrate. Together, the pilot schools provided a reasonable cross section of the school environments and student backgrounds present in the main study sample. One pilot school, located in an urban section of Los Angeles County, had a more heterogeneous, ethnically diverse student population (34% minority); the other pilot school, located on the suburban fringes of that area, had a more homogeneous, predominantly white student body (14% minority).

We employed active consent procedures in the more homogeneous suburban school because officials there had expressed concern about whether passive consent methods would adequately inform parents about the research. The second school, with more minority students, offered the potential for assessing reactions to passive consent among

those parents who the HSPC believed might be particularly concerned about protecting data privacy.

The demographic differences between the two schools, as well as the age of the students involved (grade 7) and the nature of the research program, could have affected the schoolwide consent rates reported here. We particularly urge caution in drawing comparisons between the two schools. However, our most important findings rest on analyses of data gathered from parents *within* one school at a time, where the issue of between school comparisons does not arise. These results, while clearly not generalizable to all school environments, provide important new information for evaluating the two major approaches to seeking parental consent.

OBTAINING PARENTAL CONSENT

In March of 1984 we contacted the parents of 200 seventh graders at the two schools to obtain permission for including their children in the project's pilot phase. Students in the two schools were asked to provide one or more physiological samples (saliva, urine, or hair) and fill out self-administered questionnaires describing their drug use and related attitudes and behaviors.

To maximize the likelihood that parents would receive and carefully review both the passive and active consent forms, we implemented a three-stage strategy for delivering consent materials. That strategy used both mail and school channels of communication: (1) the first consent package (containing a letter describing the prevention program and research procedures, a parent fact sheet providing additional details, and a consent form) was sent directly to the parents' homes via regular first-class mail; (2) about one week after the initial mail out, a postcard reminder was sent to all parents; and (3) about three weeks after the initial mail out, all students were asked to take an additional packet home to their parents.

Several methods were used to direct parents' attention to the consent form—sending it with an introductory letter from the school principal, stamping the message IMPORTANT INFORMATION on the envelope, and translating the materials into Spanish for the district that normally uses Spanish translation. Parents could communicate their wishes by returning the form in a postage paid preaddressed envelope, calling us collect, or contacting the school directly. To allow sufficient time for parents to respond, materials were mailed to parents about four weeks before the start of the pilot data collection.

PILOT RESULTS

Overall, 90% of all parents gave permission for their child to participate in the data collection process—86% in the active consent school and 93% in the passive consent school. However, while the 86% rate for active consent is considerably higher than that typically reported in the literature, achieving it required an intensive and costly campaign.

HOW MUCH EFFORT DOES ACTIVE CONSENT INVOLVE?

That campaign involved multiple follow-ups and several different techniques for contacting parents. Besides the postcard reminder and packet distribution to students in both schools, follow-up efforts included two telephone reminder calls to all nonrespondents, two special parent meetings, and daily teacher requests for students to return missing consent forms before the program start date.

These efforts proved quite successful. Two weeks after the initial mail out and one week after the postcard reminder, only 40% of the active consent parents had returned a permission slip, a result that parallels the experience of other studies using active consent. By the end of the fourth week, we had obtained forms from *all* 86 parents, including 12 who refused consent. As Table 1 shows, the first telephone call increased the form return rate by 14%, while the second consent package (sent home with the student) yielded an additional 21%. Bringing in the last 26% required a second round of telephone calls and daily teacher reminders asking students to remind parents to return the missing forms.

This experience resembles that reported in the mail survey research literature, which suggests that multiple follow-ups using varied techniques is the most effective way to ensure high response rates to mail solicitations (Dillman, 1978; Heberlein and Baumgartner, 1978; Baumgartner and Heberlein, 1984). However, few studies are likely to have the resources or time required to implement such extensive and costly procedures for obtaining parental consent. Our two stages of telephone follow-up alone cost approximately $25 per case. In a large study, that expense would be prohibitive. For example, calling parents for a sample of 7,500 students with an initial parental nonresponse rate of 60% would cost $112,500 (4,500 parents $\times$ $25). Conducting those calls would take about 234 interviewer days (25 minutes per case for all calls to complete), requiring a minimum period of three to four weeks for a telephone center with 20 interviewer stations. In our case, such a lengthy consent process would also have delayed data collection until

TABLE 1
Follow-Up Results for Active Consent Parents

Type and Timing of Follow-Up	*Forms Returned By:*	*N*	*%*
postcard reminder (day 7)	day 14	34	39.5
first phone call to nonrespondents (day 15-17)	day 20	12	14.0
second packet via students (day 20)	day 22	18	20.9
second phone call and daily teacher reminders (day 22-25)	day 28	22	25.6
		86	100

TABLE 2
Consent Rates Under Active and Passive Consent

	Active Consent				*Passive Consent*[a]	
	No		*Yes*		*No*	
When Form Received	*N*	*%*	*N*	*%*	*N*	*%*
Before follow-up	5	5.8	29	33.7	4	3.4
After follow-up	7	8.2	45	52.3	4	3.4
Total	12	14.0	74	86.0	8	6.8

a. Total number of parents equals 117, of which 93.2% gave passive consent.

well into November, precluding the acquisition of baseline data before delivery of the prevention curriculum.

WHAT DOES PARENTAL NONRESPONSE TO ACTIVE CONSENT MEAN?

As Table 2 shows, the intensive follow-up effort for active consent parents also raised the overall consent rate, from only 34% before the campaign began to 86% when it concluded. Clearly this group of parents—52% of the total who consented and 87% of the initial nonrespondents—had not intended to object to their child's participation by failing to return a signed form. While they ultimately

approved their child's inclusion in the evaluation, they lacked motivation to sign and return the form without considerable prompting. Moreover, of the 14% who refused permission, almost half registered their veto *before* the telephone and school follow-up began. Hence, nonresponse signaled a latent refusal for only 8% of the active consent parents. For the great majority, failure to send in a form appeared to reflect latent consent combined with apathy or inertia.

DOES PARENTAL NONRESPONSE TO PASSIVE CONSENT SIGNIFY CONSENT?

While nonresponse to the active consent procedure was considerably more likely to reflect "apathetic consent" than a deliberate refusal, nonresponse to passive consent typically reflected a conscious parental decision to allow the child to participate in the research. As Table 2 shows, 8 of the 117 parents (7%) in the passive consent school eventually sent in signed forms refusing permission for the child to participate. However, only 4 of those refusals were received within two weeks of the mail out. Thus we called the remaining 113 parents to ascertain whether they had received the consent materials and understood what the data collection entailed. We reached 94 of them.

Those calls triggered only 4 more refusals, indicating that equating nonresponse with permission accurately reflected the wishes of 96% of the parents reached by phone. Moreover, in response to a structured set of questions, the great majority of those parents (87%) specifically said that they had received the materials, understood them, and decided to allow their child to participate.

Overall, therefore, the pilot procedures suggest that failure to return a form is considerably more likely to reflect latent consent than latent refusal. These findings apply no matter what the request—for a signed slip from every parent or for a signed slip only from those who object to their child's participation in the research.

DID PARENTS RECEIVE AND PAY ATTENTION TO PASSIVE CONSENT MATERIALS?

But did passive consent satisfactorily inform parents about the research? Regular first-class mail appeared to ensure parental receipt of the consent package in almost all cases. No packets were returned to participating schools as undeliverable and, as noted earlier, 87% of the passive consent parents contacted said they had received and understood

the consent materials. Of the 13% who indicated they did not remember getting a copy of the letter, all but one gave the same address provided by the school. These figures suggest that the original package was probably delivered, but that parents either misplaced it or failed to read the materials carefully.

Nevertheless, the 13% who did not remember getting a copy of the letter concerned us. All but one of these parents apparently had received the consent package but had not paid attention to it, despite our efforts to enhance its external importance and internal readability. Hence, we concluded that responsible use of passive consent requires special efforts to make sure parents both receive the consent materials and *pay attention* to it. Using different channels of communication (delivery through the school as well as by mail) is one way to do this: as the results from the active consent school showed, sending the consent packet home with students stimulated a response from a substantial proportion of parents who had ignored materials received by mail.

SUMMARY

Because each research project encompasses different substantive issues, subjects, and procedures, deciding whether passive or active consent is appropriate must proceed on a case-by-case basis. This study provides data about the effectiveness and costs of each method that should help interested parties make more informed decisions. Overall, it suggests that carefully designed passive consent procedures can inform parents while avoiding the large nonresponse rates and sample bias often associated with active consent procedures. As in other studies, active consent initially yielded an unacceptably low response rate. Raising the rate to 100% required extensive follow-up efforts that would be prohibitively expensive and time consuming for large research projects. Moreover, that effort secured few additional parent refusals, indicating that nonresponse was considerably more likely to signify latent consent than a deliberate refusal.

The pilot also showed that passive consent procedures, appropriately designed and implemented, could minimize the likelihood that parents might not receive the consent materials and improve the likelihood that they would be read. No mailings were returned as undeliverable in either school, and only one address required updating. Sending materials home with the child provided an effective backup method for getting the attention of parents who ignore mail solicitations. In addition, equating nonresponse with permission appeared to reflect the true preferences of

most parents in the passive consent school. Of the 94 parents contacted by phone, the great majority said they had received the consent package and intended their lack of response to communicate approval of their child's participation in the research. Only 4 subsequently refused permission.

Based on these findings, we recommended implementing a modified form of passive consent that would provide backup procedures for reaching parents who might not pay attention to mail solicitations. The committee approved a three-stage process that uses both mail and school channels.

DISCUSSION

Because disclosure of sensitive individual information constitutes the major risk to students who participate in drug use research, researchers need to promise confidentiality *and* deliver on that promise, whichever consent procedure they use. This guarantee has a heightened ethical dimension under passive consent, whereby the researcher takes on the added risk of mistaking nonresponse for consent and possibly exposing students to risks that their parents have not explicitly accepted. While this study suggests that the risk of falsely assuming consent is small, it does not suggest that either it or the risk of disclosure should be ignored.

The risk of mistaking nonresponse for consent can be reduced by procedures designed to increase the likelihood that parents will receive consent materials, pay attention to them, and have sufficient time to respond. Besides using multiple methods to reach parents (regular mail plus school follow-up), we found it effective to make the materials as clear and easily understood as possible, translating them when appropriate, and highlighting their importance by including a letter from the school principal and attention-getting markings on the envelope. We also allowed parents four weeks to respond. The efficacy of these procedures is underscored by our subsequent experience with over 9,500 students from eight California and Oregon school districts. During four separate waves of data collection, only one parent complained that he had not known about the research or received the consent materials.

Minimizing the risk of disclosure requires careful data safeguards in the field and at the research institution. Most important is the need to prevent the association of an individual child's name with sensitive information. Following typical practice, we kept participant names separate from their survey responses and stored the link between names

and survey IDs in a locked facility accessible only to authorized staff. When collecting data in the schools, we found it essential to restrict data collection and handling to specially trained staff, to prevent school officials or visitors from seeing student responses, and to remove all data from the school expeditiously. Because we asked about student drug use, we also applied for a Department of Health and Human Services (DHHS) confidentiality certificate that guarantees that individual data will be protected from subpoena. Four successful waves of data collection without a single violation of data privacy have supported the efficacy of these procedures as well.

Our experience suggests that passive consent, when supplemented by appropriate backup and safeguard measures, can provide a feasible and ethical alternative to active consent. Nevertheless, such decisions should not be taken lightly. To enable scientific advance without disservice to individual rights, researchers must carefully weigh the pros and cons of active versus passive consent procedures for each individual project.

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