

Recruiting Adolescents into Genetic Studies of Smoking Behavior¹

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Abstract

The goal of this study is to describe the process of establishing a longitudinal cohort to study genetic, psychological, and social predictors of adolescent smoking. Parents of eligible adolescents were approached for their consent via mail. Seventy-two percent of parents ($n = 1533$ of 2120) provided a response regarding their teens' participation. Among those who provided a response, 75% (1151) agreed to allow their teen to participate in the research yielding an overall parental consent rate of 54%. Compared with parents who consented to their teens' participation, parents who declined were less educated (89% had greater than a high school education compared with 69% of those who did not provide consent), less likely to be Caucasian (68 versus 48%), and less likely to report having ever even experimented with smoking (71 versus 60%). The most frequently reported reasons parents gave for declining consent included lack of interest and confidentiality concerns. A logistic regression model predicting consent to participate revealed a significant race by education interaction, indicating that among Caucasian parents, those with an education beyond high school were over two times more likely to provide consent compared with Caucasian parents with a high school education or less (odds ratio = 2.43; confidence interval = 1.37–4.32, $P = 0.003$).

Introduction

To identify the bio-behavioral predictors of adopting a smoking habit and who is at higher risk for smoking, longitudinal studies evaluating genetic, psychological, and social variables are necessary. This information could be used to develop more effective prevention programs, especially because social influences-based approaches to smoking prevention appear to be limited in their effectiveness (1, 2). Although longitudinal, prospective, cohort study designs may best inform us about the process of adolescent smoking adoption (3), the practical challenges as-

sociated with accruing adolescents into bio-behavioral studies are substantial (4). Furthermore, issues of privacy and heightened concern for confidentiality are often raised when genetic information is collected (5). Although numerous studies have collected biological data to validate smoking and other substance use/abstinence in adolescents (6), concerns may be more prominent when biological data are to be collected from adolescents for genetic analyses.

Both active parental consent, as well as adolescent assent, are required to gather genetic information from adolescents. Although obtaining consent and assent are critical, this process demands substantial effort and resources (7). In the future, school-based, bio-behavioral investigations may increase in number, as will the need to address issues of obtaining parental consent. Unfortunately, the existing literature offers little in the way of information and guidance for scientists seeking suggestions on effective strategies to recruit adolescents into behavioral genetics studies. Additionally, little is known about what factors would influence parents to provide consent to have their teen participate in a longitudinal, observational study evaluating genetic contributions to an addictive behavior such as smoking. A better understanding of who declines consent and for what reasons could provide valuable information for promoting recruitment.

Only a few studies have examined differences between participants and nonparticipants in school-based tobacco use research involving active parental consent (8, 9). These studies found non-Caucasian parents and parents with a lower level of education to be less likely to respond. However, interactions between race and education were not evaluated, nor were demographic differences or parental smoking history differences between those parents who actively declined and those that actively consented. We proposed to address these gaps in the literature by determining if similar relationships between demographic variables and consent to participate would be observed. Given that the present study required active written parental consent, we expected to find a similar relationship between consent, parent education, and parent race. We did not expect that consent would differ based on parental smoking history. Of particular interest was the number of parents who declined consent to participate because of concerns about the collection of genetic information.

Materials and Methods

Initiating Contact with Schools. In the initial stages of planning, an administrator in the county school district's office on safe and drug-free youth was approached to enlist support for the project and administrative approval at the school board level. Once successful, five high schools that were representative of the 21 high schools in the county were selected to participate. The principals of these five high schools were approached, oriented to the project, and subsequently offered their support. Principals also designated a study contact person within each school to facilitate requests for information, such as class rosters.

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Obtaining Student Information. The study contact person at each school provided a 9th grade class roster of students and indicated the students who were not eligible to participate because of special class placement, such as a severe learning disability or difficulty speaking and understanding the English language. Names and mailing addresses of students eligible to participate were then ascertained. Introductory letters and study consent forms were sent to students' homes, rather than relying solely on students to deliver the information to their parents (10). Ninth grade was selected as the cohort initiation point because it enabled us to prospectively determine the factors that contribute to the adoption of a smoking habit in adolescents. Although as many as 65% of adolescents have tried at least a puff or two of a cigarette in the 9th grade, only ~40% have smoked a whole cigarette, and only 10% are regular smokers by this age (11, 12). To capture adolescents before smoking initiation (*e.g.*, 6–8th grade) and then follow them to regular smoking would have required a prohibitively long follow-up period.

Contacting Parents for Consent. Mailings were sent to parents of all eligible students and included: (a) a cover letter from the school principal and study principal investigator explaining the nature and purpose of the study; (b) two copies of an informed consent form (one to sign and return and one to retain for family records); (c) a study brochure emphasizing the key elements of the project; (d) a confidential parent information form so that respondent characteristics could be described; (e) a \$5 video rental coupon which served as a study incentive; and (f) a stamped return address envelope. Parents interested in having their teen participate in the project were instructed to return the parent information form and a signed informed consent form. Parents not interested in the project were to return the parent information form only.

The informed consent described the purpose of the study, what participation in the study would involve for the teen, how the information collected would be used, and how it would be kept confidential. Teen participation in the study involved reading and signing an assent form and completing a 25-min survey on smoking, tobacco advertising, mood, personality, exercise, and alcohol and drug use. A similar survey would be repeated four times through the end of 12th grade. Participation also involved providing a cheek swab in the 9th grade for genetic analyses and providing a saliva sample at the end of the 12th grade to verify smoking status. After the completion of each survey, participants would receive a \$5 video rental coupon as a token of appreciation.

As many as three waves of mailings were subsequently sent to students' homes ~4 weeks apart in an attempt to reach nonresponders. Although exact figures on the success of each wave to bring in new information were not maintained, in general, each wave produced 20–25% of the responses. These later mailings were modified to include a bar graph on the outer envelope showing the school's study response rate, as well as special instructions for interpretation services printed at the bottom of the cover letter in the five most common languages spoken in the community in an effort to reach parents whose native language was not English.

Study Information Sessions. At the same time that mailings were being sent to students' homes, the study was actively promoted at each of the five sites. Study staff attended physical education faculty meetings to brief them on the nature of the project, answer questions about the study protocol, and provide informational handouts and a script to introduce the project to the students. This was done because the project was scheduled

to be conducted through health and PE³ classes, a required course for all 9th graders. Study staff also attended Parent-Teacher-Student Association meetings. Study staff also informed students about the study during the first 5 min of health and PE and distributed study packets to be taken home to parents. In other instances, school-wide announcements were made encouraging students to remind their parents to promptly return study materials.

Efforts To Promote Response to Study. Despite efforts to reach all parents by mail, it was necessary to use other strategies to reach parents who had not responded to mailings. Telephone numbers were distributed directly to small groups of parents of 9th graders at each school who volunteered to be trained to call and confirm that study mailings had been received and to encourage parents to respond. In return for their effort, a modest cash donation was made to the school organization of their choice.

Students were involved in between- and within-school competitions to promote the return of study forms. Freshman classes at the schools with the highest percentage of returns would be awarded a cash prize. For the within-school competition, students in the health and PE class with the highest percentage of returns would be given a pizza party. Health and PE teachers provided us with lists on a regular basis indicating which of their students' parents had or had not yet responded by returning study forms. Students were encouraged by their health and PE teachers during class periods to remind their parents to return the forms. The teacher at each school who earned the highest study response rate was awarded a nominal cash prize.

Results

Eligible participants were enrolled in the 9th grade in five public high schools in northern Virginia that were participating in the study. On the basis of the aforementioned exclusionary criteria, 89% (2120 of 2393) of the students were eligible to participate. Project information packets, including parental consent forms, a brief demographic/response form, and a letter from the school principal, were mailed to the parents/guardians of all eligible 9th graders. Seventy-two percent of the parents/guardians (1533 of 2120) provided a response, and 28% (587) did not reply. Parental response rates did not significantly vary by school. Of those parents who responded, 75% (1151) provided written consent for their adolescent to participate, and 25% (382) declined. Of the 1151 adolescents who had parental consent to participate, 99% provided assent.

Sample Characteristics of those Providing a Response. The average age of the parents who provided a response was 45 years of age ($SD = 6.2$). Over half (59%) of the responding parents were college graduates, and 79% had more than a high school education. The majority of the responses were provided by mothers (73%). The majority of the sample was Caucasian (64%), ~7% were African-American, 12% were Hispanic, 13% were Asian, and 4% were other. Most of the parents (69%) reported having experimented with cigarettes themselves (*i.e.*, at least having a puff or two). Over one-third (35%) reported smoking regularly at some point in their lifetime, and 11% reported currently smoking.

³ The abbreviations used are: PE, physical education; OR, odds ratio; CI, confidence interval.

Table 1 Reasons for declining consent (n = 251)

Reason	No.	Percentage
No interest (teen)	89	36
No interest (parent)	28	11
Confidentiality (general)	25	10
Confidentiality (genetics)	15	6
No time	26	10
Teen doesn't smoke	26	10
No benefit	13	5
Parent responsibility	8	3
Culture/religion	3	1
Risk of smoking	6	3
Other	12	5

Differences between Parents who Consented and Parents who Declined. Compared with parents who consented to their teens' participation, parents who declined were less educated [$\chi^2(1) = 13.41, P = 0.0003$]. About 81% of those parents providing consent had more than a high school education, compared with 69% of those who did not provide consent. Parents who provided consent to their teens' participation were also more likely to be Caucasian [$\chi^2(1) = 31.47, P < 0.0001$]. Sixty-eight percent of parents who consented were Caucasian, whereas 48% of parents who declined were Caucasian. Although the majority of forms were returned by a mother, there were no significant differences in consent if the forms were returned by the father ($\chi^2(1) = 2.62, P = 0.25$). Furthermore, there were no differences in consent based on teen gender ($P > 0.40$) or teen gender stratified by parent gender ($P > 0.20$).

Compared with parents who consented to their teens' participation, parents who declined were less likely to report having ever smoked themselves ($\chi^2(1) = 11.57, P = 0.0007$), *i.e.*, 71% of those who consented reported at least experimenting with cigarettes compared with 60% of those who declined. There were no differences in consent based on whether a parent had regularly smoked or parents' current smoking practices ($P > 0.60$).

We coded the reasons parents gave for declining permission to have their teen participate. About 251 parents of 382 provided a reason. Reasons were coded into 10 categories by two independent raters. Among the primary reasons offered for declining, the coding scheme achieved 85% accuracy, indicating good inter-rater reliability. The most frequently reported reasons parents gave for declining consent included lack of interest, confidentiality concerns, time, and that their teen does not smoke. (Table 1).

Multivariate Model of Parental Consent for Participation.

We conducted a multivariate logistic regression analysis in which all variables with a bivariate association ($P < 0.10$) with consent to participate were considered in the model. The model included education, race, experimentation with smoking, and race by education interaction. The results revealed that the race \times education interaction was the only significant independent predictor of consent (OR = 2.51; CI = 1.22–5.15, $P = 0.013$). Table 2 summarizes these findings. Logistic regression stratified by race was used to characterize the interaction. Among the Caucasian parents, those with an education beyond high school were over two times more likely to provide consent compared with Caucasian parents with a high school education or less (OR = 2.43; CI = 1.37–4.32, $P = 0.003$; Fig. 1).

Table 2 Logistic regression model of parental consent for teen to participate

Variable	OR	CI
Education (\leq HS vs. $>$ HS)	0.96	0.63–1.50
Race (other vs. Caucasian)	0.94	0.50–1.77
Smoking experimentation (yes vs. no)	0.80	0.58–1.11
Race by education ^a	2.51	1.22–5.15

^aSignificant at $P < 0.05$.

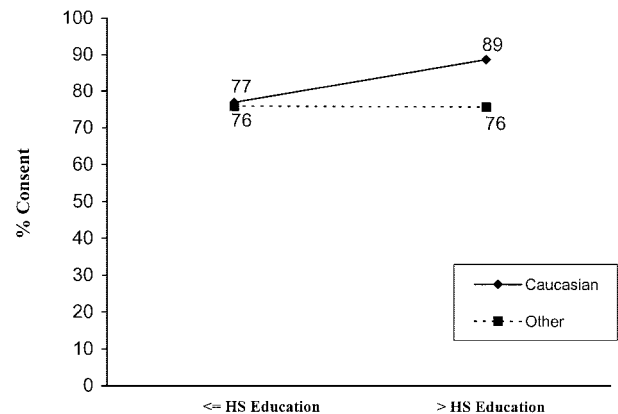


Fig. 1. Consent to participate by education and race.

Discussion

The goals of the present study were to describe the process of establishing a longitudinal cohort to evaluate the bio-behavioral predictors of adolescent smoking, present information on parental consent rates, characterize parents who were more likely to consent/decline to their teens participation, and examine reasons for declining. The study response rate was 72%. This response rate included a consent rate of 54%, a decline rate of 18%, and a nonresponse rate of 28%. The active consent rate is consistent with, although in some instances lower than, those of other studies investigating adolescent health topics in school settings (7, 8, 9, 13). The rate of nonresponse is also similar to that observed in other studies (14). This relative consistency in response and consent rates is important to note because unlike the studies listed above, the current study does not involve an intervention, and data were collected for genetic analyses.

Parents who consented to their teens' participation were more likely to be Caucasian and have more than a high school education. In fact, these parents were over two times more likely to provide consent compared with Caucasian parents with a high school education or less. Youth of parents who are less educated are often underrepresented in adolescent research (13), including tobacco studies (8). This might suggest the study-related information, such as the informed consent form, may have been overwhelming for some parents, although the cover letter and brochure were written with variable literacy levels in mind. Alternatively, this finding may reflect generalized apathy or disinterest in research or misunderstandings about what the research really involves (13).

Parent educational and ethnic response differences have been reported in prior school-based studies that involved active parental consent (8, 15), although we found no prior studies where interactions between these two variables were evaluated. Of interest is that the level of parental consent among non-Caucasian parents did not vary by education. Our sample of

students is representative of the student population from which it was drawn. This may be because we addressed a large participation barrier faced by parents of different racial and ethnic groups. The largest barrier in a diverse population is communicating to parents whose first language is not English. This was addressed in the current study by having staff members and parent volunteers who spoke other languages (*e.g.*, Spanish and Farsi). To boost minority recruitment further, cultural issues (*e.g.*, parental responsibility to address health habits and mistrust of research) may need to be addressed.

Information collected from parents who chose not to have their teenagers participate in this study revealed that lack of interest in the aims of the project was a commonly cited reason for declining (47%). Furthermore, lack of interest in the study on the part of adolescents was almost three times more likely than was no interest on the part of their parents. This suggests that family members at least briefly discussed the project with one another before making their decision. It also indicates that parents generally respected the decisions of their teens regarding participation. Thus, promoting project awareness and interest among potential teen participants appears to be important for promoting parental consent rates, because parents will not provide consent if their teen is not interested in participating. Although lack of interest is a valid reason for not participating in research, it remains vague. Teens considering participation may have been concerned about the use of the information (biological and nonbiological) and possible consequences despite assurances of confidentiality (16).

About 16% of parents did not provide consent for their teen to participate because of concerns about confidentiality. Almost half of the respondents who cited confidentiality raised specific concerns about the DNA sample being collected in this study, and the rest reflected nonspecific concerns over data privacy. Confidentiality regarding adolescent genetic testing was less of a concern than we had initially anticipated. Fewer concerns may have been raised because this research was observational, the genetic sample was obtained through a non-invasive buccal swab, no one would receive feedback regarding genetic results, the project was federally funded and approved by the school board and the Institutional Review Board, and the project carried a Certificate of Confidentiality on behalf of the United States Department of Health and Human Services. However, we cannot rule out that parents who did not respond at all or many of the parents who were not interested had unexpressed concerns about the collection of genetic information.

In conclusion, this study provides a first step in describing the process of recruiting adolescents into studies evaluating the genetic contributions to smoking. This is important in that it is likely that these types of studies will become more widespread with advances in behavioral genetics. The findings of the present study suggest that the issues confronted by adolescent studies involving the collection of genetic data are comparable with those studies that investigate other adolescent health topics that require active parental consent, *i.e.*, the sample of parents

in the current study tended to have a higher level of education, which may limit generalizability. Recruitment strategies need to target the participation barriers faced by teens and parents with less education.

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