The Role of Parental Consent in Adolescent Substance Use Research

Neal L. Rojas, M.D.*, Lon Sherrit, M.P.H., Sion Harris, Ph.D., and John R. Knight, M.D.

Center for Adolescent Substance Use Research, Children’s Hospital Boston, Boston, Massachusetts

Manuscript received April 30, 2007; manuscript accepted July 21, 2007

Abstract

Purpose: The objective of our study was to assess the effects of requiring parental consent upon study participation and self-reported substance-related problems among 14–18-year-olds.

Methods: This was a secondary analysis of combined data from two similar studies of adolescent substance use that recruited participants from the same adolescent clinic at Children’s Hospital Boston. Study 1 waived parental consent, whereas Study 2 required parental consent. The combined dataset included demographic characteristics and Car, Relax, Alone, Forget, Friends, Trouble (CRAFFT) study screening test responses. The CRAFFT is an orally administered screen that yields a score from 0–6 and that has been shown to be a valid and reliable measure of risk for substance-related problems.

Results: The participation refusal rate in Study 1, where consent was waived, was 19.7% (132 of 670 eligible individuals) and in Study 2 (243 of 411 eligible individuals), where consent was required, it was 59.1% (p < .0001). Participants did not differ significantly with respect to gender and age but did differ by self-identified race/ethnicity between the two studies. Because the CRAFFT score distributions were highly skewed, we used the nonparametric Mann-Whitney U test for differences in mean rank. The mean rank in Study 1 was significantly higher than in Study 2 (mean rank 362 vs. 325, p = .02). After controlling for age, gender, and race/ethnicity, the adjusted proportional odds ratio for a one-point increase in CRAFFT score was 1.47 (CI 1.03, 2.10) for Study 1 compared with Study 2.

Conclusions: The research requirement of parental consent may result in substantial self-selection bias towards a lower risk sample. © 2008 Society for Adolescent Medicine. All rights reserved.

Keywords: Parental consent; Adolescence; Research; Substance abuse

Studies of adolescent substance use have grappled with the issue of parental consent for several decades [1–19]. Obtaining permission from parents for participation in research may improve adherence with study protocols, enhance parent–child communication, and promote trust and respect among family members [20,21]. However, when studying high risk behaviors such as sexual activity or substance use, waiving the requirement for parental consent may be necessary to ensure confidentiality and safety, maximize study participation, and reduce self-selection bias.

Active parental consent requires that study personnel contact the parent or legal guardian, explain the study procedures, risks, and benefits, and obtain either a signature or verbal authorization before the adolescent enters the study. So-called passive consent allows investigators to notify parents of all potential research participants about research in advance and assume consent unless further notified by a parent that he/she does not agree to participation. This typically involves, in the case of school-based research, a letter sent out to all parents [17]. The term “assent” is generally used to refer to obtaining an adolescent’s permission in addition to parental consent [13].

Federal regulations protecting minors in research currently allow waiving, altering, or substituting active consent with passive consent procedures if the following four conditions are met: (1) “the research involves no more than minimal risk to the subjects; (2) “the waiver or alteration
will not adversely affect the rights and welfare of the sub-
jects’; (3) “the research could not practicably be carried out
without the waiver or alteration”; and (4) “whenever appro-
priate, the subjects will be provided with additional perti-

A small number of school-based studies have directly
or indirectly assessed the effect of parental consent on
adolescent substance use research [18,23–28]. Each study
compared self-report of substance use by students be-
tween two groups assigned by the school to either active
parental consent or passive parental consent. In all of
these studies the investigators found that, compared with
the passive consent group, the active consent group had
lower rates of self-reported tobacco, drug or alcohol use.
Two of these studies were conducted among younger
middle school students and addressed smoking behaviors
only [23,26].

Less is known about the effects of requiring parental
consent in studies of older adolescents with more substance
use. High school students may be more cognitively capable
of making informed decisions, and less inclined to partici-
pate if parents are involved [20,21]. In one study of high
school student self-reported drinking practices, active con-
sent procedures resulted in under-representation of lifetime
drinkers and high-risk drinking [24].

A recent review of literature pertaining to parental con-
sent in adolescent risk behavior research concluded that
active consent typically results in only 30–60% participa-
tion rates compared with much higher rates among studies
using passive consent (93–100%) [1]. Lower rates of ethnic
minority participation were also associated with active pa-
rental consent procedures. Although it seems that compared
with passive consent, obtaining active parental consent re-
sults in lower participation and potential bias, we could find
no studies comparing active parent consent to a complete
waiver of the requirement for parent consent.

Although school-based studies provide convenient and
large samples of adolescents, their findings may not gen-
eralize well to studies conducted in clinical settings
and studies that include assessment of substance-related
health concerns. Furthermore passive consent procedures
are seldom used for adolescent research in clinical set-
tings because of trends in IRB practices [2]. Few studies
to date have explored the effect of parental consent upon
study participation and sample characteristics in clinical
populations of adolescents studied for substance use
risks.

The objective of our study was to assess the effects of
requiring parental consent versus obtaining a waiver of the
requirement for parent consent on study participation and
sample characteristics among 14–18-year-old clinic patients
invited to participate in substance use research. We hypo-
thesized that parental consent would result in lower study
participation and a sample biased toward lower substance
abuse screening test scores.

Methods

This study was a secondary analysis of combined data
from two studies of adolescent substance use that recruited
participants from the same adolescent clinic at Children’s
Hospital Boston. Study 1 waived parental consent, whereas
Study 2 required parental consent. Initially, the Children’s
Hospital Boston Committee on Clinical Investigations (in-
stitutional review board) waived the requirement for par-
ternal consent for Study 2. However, during the process of peer
review of the National Institutes of Health grant application,
reviewers raised a human subjects concern regarding the
planned waiver, which could have precluded funding. As a
result, the investigators changed the protocol to include
parental consent. This was a strategic decision, which may
have ultimately hindered the generalizability of the study
because of under-representation of substance use problems
in the sample obtained.

The purpose of Study 1 was to validate the Car, Relax,
Alone, Forget, Friends, Trouble (CRAFFT) study substance
abuse screening test among 14–18-year-old patients coming
for routine medical care. The CRAFFT is a six-item screen-
ing test for substance-related problems and disorders in
adolescents. The study was conducted from 1 March 1999
to 14 September 2000 in the Adolescent/Young Adult Med-
ical Practice (AYAMP) at Children’s Hospital Boston. This
practice serves both inner city and suburban youth from a
wide range of social strata, racial groups, and ethnic back-
grounds. For Study 1, the Children’s Hospital Boston Com-
mittee on Clinical Investigation (institutional review board)
waived the requirement for parental consent in accordance
with guidelines for adolescent health research previously
published in this journal [4,5,14,22].

After determining eligibility, the medical care provider
invited patients to participate at the conclusion of the med-
ical visit. Study staff then approached these patients for
informed assent. Patients were told that the purpose of the
study was to assess the value of screening questions on use
of alcohol and other drugs. Patients with cognitive impair-
ments, severe illness, or who were non-English reading
were excluded (n = 9). Participants received a $25 mer-
chandise certificate as compensation for their time.

The purpose of Study 2 was to assess the association
between adolescents’ substance use and spirituality. This
study recruited a consecutive sample of 12–18-year-old
patients arriving for routine care between 1 May 2001, and
30 April 2002 at the AYAMP site at Children’s Hospital, as
well as two other clinic sites. Only AYAMP data, however,
and data on 14–18-year-old participants were analyzed for
this report. Similar to Study 1, participants were recruited
by clinicians and approached by study staff for assent.
Participants were told that the purpose of the study was to
assess the relationship between spirituality and alcohol/drug
use and that their answers would be kept confidential.
Interested patients met with a research assistant, who ex-
explained the study procedures and obtained parental consent, either in person or by telephone, as well as signed adolescent assent on the day of the clinic appointment. Patients whose parents could not be reached to provide consent were excluded (n = 16). Patients with severe illness (n = 18) or unable to read English at a sixth-grade level or cognitively impaired (n = 14) were also excluded. As in Study 1, participants received a $25 merchandise certificate as compensation for their time.

The two studies had a number of key similarities. Both were conducted in the same practice and included adolescent patients who were arriving for routine primary care appointments. In both studies, the charts of age-eligible patients were flagged by a research assistant. The primary care provider introduced the study to the patient at the conclusion of the medical visit, and referred interested patients back to the research assistant (RA). The RA explained the study purpose and procedures and obtained informed assent from the teen as well as administered the study questionnaires on the same day of the medical visit. The composition of clinical staff was nearly identical between studies. In both studies, patients who were medically unstable OR could not read and understand English at a sixth grade level because of cognitive impairment were excluded.

The primary difference between the two studies is that Study 1 obtained a waiver of parental consent from the institutional review board (IRB), although Study 2 required informed consent from parents in person who accompanied their child to the clinic and by telephone from parents who did not. However the RA obtained adolescent assent first, so that teens in Study 2 were told that we would speak with their parents to obtain permission as part of the informed assent process. The composition of research staff (RAs) was different between the studies although research supervisors were the same. The two studies had different purposes; Study 1 was to validate the CRAFFT, a six-item screening test for substance-related problems and disorders in adolescents. Study 2 was to explore the relationship between spirituality and substance use.

Both measurement batteries included a demographic questionnaire and the CRAFFT screening test. Study 1 included a lengthy personal interview, with a short supplemental questionnaire, while Study 2 included a short interview with a long questionnaire. Nonetheless, the approximate completion time for both studies was similar and less than 1 hour.

Analysis

We examined study recruitment logs to obtain information on participation and refusal rates for both studies. Separate databases for each study were maintained during recruitment and data analysis of the original studies. For this comparison study, we created a combined dataset by including all participants from Study 1 (N = 538) and those participants from Study 2 (N = 168) who were in the 14–18-year-old age range (we excluded 12- and 13-year-olds) and who were recruited at the AYAMP site.

The combined dataset included variables common to both individual datasets, including demographic characteristics and CRAFFT test responses. The CRAFFT is a six-item orally administered screening test that yields a score from 0–6, which has been shown in previous studies to be a valid and reliable measure of risk for substance use problems [29,30]. A score of 2 or higher is predictive of a DSM-IV substance use disorder (positive predictive value increase in a step-wise fashion from 50–99%) [29,30].

Data were checked for proper and consistent coding before merging. Frequencies and means for comparable variables were computed. Summary statistics (t-tests for means of normally distributed variables and Fisher exact tests for proportional comparisons) were used to assess differences between the two study samples. In addition we used ordinal regression analysis to evaluate the association between study status, an indicator variable for the parental consent requirement, and CRAFFT score, while controlling for age, gender, and race/ethnicity.

Results

Recruitment and demographic differences

Of 670 eligible patients, 538 (80.3%) agreed to participate in Study 1, compared with 168 of 411 (40.9%) of eligible participants in Study 2. Accordingly, the refusal rate in Study 1, where consent was waived, was 19.7% and in Study 2, where consent was required, it was 59.1% (p < .0001). In Study 1, reasons most commonly cited for refusing included “not enough time,” “not interested,” or “came with a parent.” Reasons for refusal in Study 2 were similar and are summarized in Figure 1 with the results of recruitment for each study.

Participants did not differ significantly between the two studies with respect to gender and age. A majority in both studies were female (68.4% vs. 73.2% for Study 1 and Study 2, respectively, p = .138), and the mean age was similar (16.6 years vs. 16.5 years for Study 1 and Study 2, respectively, p = .6). However, the self-identified race/ethnicity profile of participants in the two studies differed significantly (Table 1). The Study 1 sample (which waived parental consent) had more than a threefold higher proportion of white non-Hispanic participants compared with the Study 2 sample. Study 2 (which required parental consent) had nearly twice the proportion of black non-Hispanic participants and almost twice the proportion of Hispanic participants compared with Study 1. The demographic composition for sex and race/ethnicity of Study 1 was very similar to the AYAMP clinic population at large. For Study 2, however, there were higher proportions of...
African-American and Latino participants compared with the greater clinic population.

**CRAFFT score differences**

Because the CRAFFT score distributions were highly skewed, we used the nonparametric Mann-Whitney U test for differences in mean rank. The mean rank in Study 1 was significantly higher than in Study 2 (mean rank 362 vs. 325, \( p = .02 \)). We also compared the proportion of participants in the two studies who had a CRAFFT score of 2 or more, which is considered a positive CRAFFT screen (significant risk of having substance-related problems or disorder). The proportion (95% confidence interval) in Study 1 was 24.5% (21.0, 28.4), whereas in Study 2 it was 19.0% (14.8, 23.9). This difference did not reach the level of statistical significance (\( p = .085 \)). As dichotomizing the CRAFFT score may reduce power to detect clinically important differences, we also conducted an ordinal regression (Polytomous Universal Model) analysis using CRAFFT score as the ordinal dependent variable. This technique also helped to address limitations to power resulting from the relatively smaller sample size of Study 2 (\( N = 168 \)) compared with Study 1 (\( N = 538 \)). The parental consent requirement was significantly associated with CRAFFT score (\( p = .03 \)). After controlling for age, gender, and race/ethnicity, the adjusted proportional odds ratio for a one-point increase in CRAFFT score was 1.47 (CI 1.03, 2.10) for Study 1 compared with Study 2.

**Discussion**

This study suggests that parental consent may negatively affect study participation in adolescent health risk behavior research, and that it may result in substantial self-selection bias towards lower substance abuse risk reporting. The study that required parental consent had a much higher refusal rate and significantly lower CRAFFT scores, meaning less substance-related risk. The study that required parental consent also had a significantly higher proportion of black and Hispanic participants.

A mounting body of evidence mainly from school-based adolescent risk behavior research shows higher participation rates with passive parental consent procedures [1,27,28]. Our study is unique in showing that, within a clinical research setting, decreased adolescent participation is also found when active parental consent is required, compared with adolescent assent alone. This finding, however, is quite consistent with school-based studies that have shown decreased reporting of substance use and substance related behaviors when active parental consent procedures are used. Furthermore our study adds to the literature by using a well-validated clinical screening instrument as the outcome variable.

Our study contrasts with previous studies in finding that...
minority research participants were overrepresented in the study that required parental consent [1,27,28]. This may have occurred for several reasons. First, our population in the AYAMP clinic is already a very diverse sample of urban and suburban adolescents, and the size was such that it allowed statistical power to detect differences in proportions. In addition the purpose of Study 2, which was to explore the relationship between spirituality and drinking, may have appealed more to ethnic minority participants than to white patients. Several studies have previously shown a tendency of African American and Hispanic/Latino populations to endorse spiritually based health-related behaviors [1,31]. Additional evidence supports the notion that parental consent perceptions of teens and their parents may vary among different ethnic groups [32].

A higher proportion of minority participants in Study 2 could also partially explain why CRAFFT scores are lower, since drug and alcohol use rates tend to be lower among black adolescents compared with white and Hispanic adolescents [33]. A fourth possibility exists, as seen by Frissell et al, that parental consent was much less appealing or possible among non-minority patients [24]. Future studies should assess the mechanisms of the bias of parental consent across different racial and ethnic groups, as well as across various risk behaviors.

This study had several methodologic limitations. First, it was a secondary analysis of two previously conducted studies, rather than an experimental study; therefore causality cannot be determined. Second, the two studies had very different purposes and were conducted at different times. Study 1 was intended to validate a substance abuse screening test, whereas Study 2 was intended to assess the association between adolescents’ substance use and spirituality. It is therefore possible that differences in study participation were caused by differential attractiveness of the study purposes. Third, the study analysis was based on a single clinic site. Other clinical populations might respond differently. Finally, we cannot exclude the possible confounding effects of study fatigue during Study 2. That is, both study recruiters and clinic patients may have tired of our previous research (i.e., Study 1) and other studies conducted in the same clinic, thereby reducing enthusiasm for Study 2 and increasing the refusal rate. Furthermore, it is possible that a few patients were asked to participate in both studies, but because of the confidential nature of the database we are unable to identify the exact number.

These limitations notwithstanding, our findings suggest that required parental consent may result in substantial self-selection bias, that is, a bias toward a lower risk sample. Alternatively, requiring parental consent may have caused self-censure resulting in lower reported substance use risk. Our study also showed differences in substance related risk behaviors that are likely to be clinically significant. The effect estimate for requiring parent consent was a lowering of .36 point on the 0–6 scale of the CRAFFT total score. This is a potentially robust effect, as the CRAFFT, when used in typical adolescent clinic populations, has a median value of only 1 [29]. Clinically different substance use profiles may exist between adolescents who chose to involve or not involve their parents in research.

Varying interpretations of federal regulations concerning the possible waiver of parental consent in research on minor children can lead to differences in determinations between review bodies. A 1995 report by Mammel and Kapplan reported that “seventy percent of respondent IRBs required parental consent for all research on minors.” This survey also showed that only 48% of IRBs surveyed nationally waive active consent in adolescent research. These figures may not accurately reflect IRB trends, given that only 39% responded to their survey over 10 years ago [2]. It may be time to reconsider IRB practices to reflect the increasing body of evidence supporting the granting of waivers of the requirement for parental consent in minimal-risk adolescent research.

Our findings have implications for future adolescent research. If we are to make significant advances in developing and testing new treatments for adolescent substance use, the issue of waiving parental consent is of primary importance. This view is supported by a report by Mammel and Kapplan, who concluded that “federal regulations need to be clarified for meaningful and necessary research on adolescents to take place” [2]. It may be time for a new look at this important issue on a federal level, and time to develop guidelines under which parental consent can be waived. We support further efforts in this direction that will promote ethical and scientifically valid future studies of substance abuse and other adolescent risk behaviors. In the future, prospective study designs that further reveal the mechanisms of self-selection bias among adolescents may also prove useful.

Acknowledgments

The authors thank the CeASAR Clinical Research Staff, Noelle Huntington, Ph.D., and Eugenia Chan, M.D., M.P.H. This study was supported by the National Institute on Alcohol Abuse and Alcoholism (grant R21 AA13029; co-sponsor: the Fetzer Institute). Other support provided by a grant (to N.R.) and grant 5T20MC000-11-06 (J.R.K.) from the Maternal and Child Health Bureau; by grant K07 AA013280 from the National Institute on Alcohol Abuse and Alcoholism (J.R.K.); grant R01 AA12165 (co-sponsor: SAMHSA), grant R01 DA104553 (L.S., S.H., J.R.K.) from the National Institute on Drug Abuse, and the National Institutes of Health Loan Repayment Program (J.R.K., N.R.).

References


