

Regular article

# Parental consent in adolescent substance abuse treatment outcome studies

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## Abstract

No systematic review has focused on parental consenting procedures used in adolescent substance abuse treatment outcomes research. To address this gap, we examined parental consenting procedures in adolescent outcome studies ( $n = 34$ ) published between 1980 and 2007. Although parental consent was required in 89% of adolescent treatment outcome studies we reviewed, consenting procedures were not routinely reported. We argue that parental consenting procedures should be routinely reported as a methodological feature of adolescent treatment outcome studies and, given concerns about sample bias in adolescent risk behavior research when parental consent is required, encourage outcomes researchers in this area to prospectively study the impact of consenting procedures on both the study participation rates and substance use reporting. © 2009 Elsevier Inc. All rights reserved.

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## 1. Introduction

Adolescent substance abuse is as a major problem that incurs a large cost to society (Miller, Levy, Spicer, & Taylor, 2006). However, it is only recently that researchers have focused their attention on developing psychosocial treatments that meet the specific developmental needs of adolescents (Muck et al., 2001). The lack of research has prompted both the Substance Abuse and Mental Health Service Administration and the National Institutes of Health (i.e., National Institute on Drug Abuse, National Institute on Alcoholism and Alcohol Abuse) to fund a significant number of efficacy and effectiveness trials that are rapidly appearing in literature (Dennis et al., 2004; Henggeler, Clingempeel, Brondino, & Pickrel, 2002; Liddle et al., 2001; Smith, Hall, Williams, An, & Gotman, 2006). This increased activity is encouraging as researchers struggle to identify evidence-based practices that can mitigate the myriad personal and social consequences of substance abuse by adolescents.

This line of research, however, is replete with complex ethical and legal issues that are rarely addressed in substance abuse specialty journals (Brody & Waldron, 2000). With regard to parental consenting procedures, these studies exist at the crossroads of federal substance abuse treatment laws (42 CFR § 2) permitting adolescents to obtain treatments without parental consent and the research regulations (45 CFR § 46, the Common Rule) specifying under what circumstances minors may consent to their own research participation. Unfortunately, although much has been written about parental consent in the broader literature on adolescent risk behavior and medical research (Collogan & Fleischman, 2005; Fletcher & Hunter, 2003; Levine, 1995; Society for Adolescent Medicine, 2003; Wagener et al., 2004), no systematic review has documented parental consenting procedures in adolescent substance abuse treatment outcome studies. Given the recent growth in adolescent substance abuse treatment outcomes research, as well as findings from adolescent risk behavior research that sample bias may occur when active parental consent is required, it is imperative that we understand how these studies have addressed the issue of collecting parental consent.

We begin by briefly reviewing the laws governing both adolescents' participation in research and substance abuse

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treatments. We then discuss findings from the broader literature on adolescent risk behavior research showing that participation rates and reporting of risk behaviors are influenced by parental consenting procedures. Finally, we report findings from our systematic review and recommendations for future research that may shed light on whether current consenting procedures are impacting the generalizability of findings in this area.

## 2. Laws governing research and treatment participation by minors

### 2.1. Adolescent participation in substance abuse treatment

State and federal laws on the confidentiality of substance abuse treatment records specify under what conditions an adolescent may receive treatment without parental notification or involvement. In general, the federal legislation on confidentiality of substance abuse treatment records (42 CFR § 2) defers to state law on deciding at what age an adolescent may consent to receive treatment without parental knowledge. When states allow adolescents to consent to their own treatment, this federal substance abuse treatment confidentiality law strictly prohibits treatment agencies from releasing records directly to parents (42 CFR § 2.15(d)) or to third party insurance companies when parents are the policy holders (42 CFR § 2.15(e)), except in limited and vaguely defined circumstances where the adolescents present a danger to themselves or others. Similarly, the Health Insurance Portability and Accountability Act also preserves the confidentiality of adolescents' health care records from parents when, by state law, they have the right to consent to their own treatment (Office of Civil Rights, 2006). Although we only focus on parental consent here, Brooks (1999) and Brody and Waldron (2000) provide comprehensive reviews of additional legal and ethical issues beyond the scope of this article.

The legal age at which minors can consent to their own treatment varies by state. As of 2004, nearly all states (i.e., 45/50, 90%) had laws permitting minors to consent to their own treatment, with 14 as the modal age of consent (Weisleder, 2004). Interestingly, it is unclear what sources of evidence lawmakers used when writing these pieces of legislation and whether empirical studies were considered (Weisleder, 2007). What is clear, however, is that the variation in age of consent for substance abuse treatment complicates study design issues for researchers who may be conducting multisite trials in different states or are consenting youth aged 11 to 13 years for whom institutional review boards (IRBs) typically require assent and parental consent (i.e., limited comprehension of study risks).

### 2.2. Adolescent participation in research

In survey research and other adolescent risk behavior research studies that do not involve the provision of

psychosocial treatments, there are several criteria specified by the Common Rule that must be met to waive the need for parental consent. Researchers may obtain a parental consent waiver if the research (a) evaluates state or local programs and the public benefit of such programs, (b) could not be practically conducted if consent were required, (c) poses no more than minimal risk to participants, (d) does not affect the rights or welfare of participants, and (e) is conducted in a manner in which additional pertinent information on the study is given to participants after participating. Researchers who study adolescent behavior and IRB members are frequently at odds over how to interpret these criteria.

In addition to outright waivers of parental consent, researchers may obtain a waiver of documentation of parental consent. Many researchers are more familiar with terms *active* and *passive* parental consent, where the former requires direct parent approval of study involvement (i.e., received explanation of study, provided original signature) and the latter assumes tacit parental approval until a parent or other guardian rescinds permission after receiving a notification letter (Jason, Pokorny, & Katz, 2001). According to the Office for Human Research Protections (OHRP), most researchers who describe passive parental consenting procedures, which are common in school-based survey research, are really describing studies for which a waiver of documentation of parental consent was obtained. Such waivers may be granted only when a study involves minimal risk and the only identifier linking the participant to their responses would be the informed consent document.

For research involving substance abuse treatment, when adolescents may consent to their own treatment, it may obviate the need to meet the criteria listed above for obtaining a parental consent waiver. The regulatory agency overseeing the interpretation of federal human subjects legislation has clearly indicated that if a research protocol studies a treatment for which the youth may consent to receive, they are not considered minors under this legislation (45 CFR § 46.402 (a); OHRP, 2008). Thus, IRBs may attempt to apply the Common Rule criteria when evaluating requests for parental consent waivers, although they are rendered inapplicable in states where youth can consent to their own substance abuse treatment and are not considered children. Interestingly, despite the apparent legal right of minors to consent to outcomes research on substance abuse treatments, 70% of university IRB chairs surveyed nationally have indicated that they always require parental consent for adolescent participation in research (Mammel & Kaplan, 1995).

## 3. Participation rates and underreporting risk behaviors

Empirical research has yet to directly evaluate the potential consequences of these seemingly conservative human subject reviews on the quality of the findings in adolescent substance abuse treatment trials. However, there is reason to believe that always requiring parental consent

in adolescent substance abuse treatment outcome studies may result in sampling biases and lower participation rates. What follows is a summary of these findings from the broader literature on adolescent risk behaviors, including nationally representative epidemiological surveys, other school-based survey research, and one report comparing participation rates and alcohol screening scores from two primary-care-based alcohol screening studies with different consenting requirements.

### 3.1. National epidemiological studies

Two studies have used nationally representative epidemiological survey data to examine the impact of parental consenting procedures on participation rates and risk reporting. Differences in parental consenting procedures have been cited as an explanation for the higher prevalence rates of substance use among those surveyed in the Monitoring the Future Study (MTF) versus those in the National Survey of Drug Use and Health (NSDUH; Fendrich & Johnson, 2001). For example, among 10th graders in the MTF, the lifetime rates of cigarette, alcohol, and marijuana use were 13.3%, 22.8%, and 16.6% higher than those reported in the NSDUH study. In the NSDUH study, active parental consent is collected, and youth are surveyed at home. However, because of other differences between the surveys (i.e., data imputation, use of private computer assisted self-interviewing, exclusion of dropouts in MTF), it was impossible to fully attribute these differences to parental consenting procedures. In the Youth Risk Behavior Survey, about 10% fewer youth participated in schools where active parental consenting procedures were used, but no differences in alcohol or drug use reported existed between schools using different consenting procedures (Eaton, Lowry, Brener, Grunbaum, & Kann, 2004). It is impossible to know, however, whether the adolescents excluded for failure to return consents were drug users.

### 3.2. School survey research

Studies have shown that the manner in which parental consent is collected impacts both participation rates and demographic characteristics of samples, but findings are mixed with regard to whether different consenting procedures result in lower reports of drug use and other risk behaviors (Anderman et al., 1995; Eaton et al., 2004; Esbensen, Miller, Taylor, He, & Freng, 1999; Frissell et al., 2004; Henry, Smith, & Hopkins, 2002; Jason et al., 2001; Kearney, Hopkins, Mauss, & Weisheit, 1983; Severson & Biglan, 1989; Severson & Ary, 1983; White, Hill, & Effendi, 2004). For example, passive consenting procedures often yield adolescent participation rates around 90%, whereas studies requiring active parental consent usually have participation rates ranging from 30% to 60% (Frissell et al., 2004). More recent studies, however, that use rigorous methods to collect active parental consent can result in good participation rates (i.e., >70% of all

eligible) and have not resulted in substantially lower risk behavior reporting (Esbensen, Melde, Taylor, & Peterson, 2008; Ji, Pokorny, & Jason, 2004).

Some, but not all, school-based studies have found lower reports of drug use or other risk behaviors among students for whom active parental consent was required. Frissell et al. (2004) saw consistently lower reporting of high-risk drinking behaviors from students in schools that required active parental consent compared with those that only required passive consent. Three additional studies found lower reported drug use in active consenting conditions for some but not all types of drugs (Anderman et al., 1995; Esbensen et al., 1999; Severson & Ary, 1983), and a separate study found that active consenting resulted in lower drug use reporting only for younger adolescents (White et al., 2004). However, one study found lower reports for only 2 of 26 risk behaviors (i.e., inadequate fruit/vegetable consumption, sports participation) in schools collecting active parental consent (Eaton et al., 2004), with no differences on substance use prevalence. In this study, participation rates were 10% lower in the active consenting schools, and authors noted they could not directly estimate risk behaviors among students that did not participate. In one study that made such direct comparisons, drug use prevalence was higher among nonconsenting youth compared with youth whose parents provided active or passive consent (Esbensen et al., 1999). Furthermore, a perfect rank order existed in this study where drug use was highest for nonconsenting youth, lower for passive consenting youth, and lowest for youth whose parents provided active consent.

In addition, studies have found that the use of active consenting procedures has resulted in less diverse and lower risk samples. For example, when comparing the demographic characteristics of adolescent participants whose parents consented to participation to students whose parents either refused their participation or did not return consents, adolescents whose parents consented had significantly fewer absences, higher grade point averages, and were less likely to be involved in special education (Henry et al., 2002). Similarly, two other studies have found differences between active consent and passive consent samples, including lower ethnic minority representation, higher grade point averages, and higher likelihood of living in two parent families (Anderman et al., 1995; Kearney et al., 1983). These differences are concerning because school bonding is a risk factor for substance use initiation (Hawkins, Catalano, & Miller, 1992). It is worth noting again, however, that studies that have managed to maximize participation rates have not seen major differences in sample composition (Esbensen et al., 2008).

### 3.3. Clinical samples

It appears that no substance abuse treatment study and only one screening and brief intervention study has directly compared the participation rates, sample demographic

characteristics, and substance use reporting under varied parental consenting conditions (Rojas et al., 2008). In fact, this study was only possible because concerns were raised about obtaining a parental consent waiver for the second study (Study 2), which used an identical substance use screening protocol as a prior study (Study 1) conducted with a parental consent waiver. In Study 1, 80.3% of eligible adolescents participated versus 41% in Study 2, which required active parental consent (Rojas, Sherritt, Harris, & Knight, 2008). Furthermore, there was a higher proportion of White adolescents and fewer Hispanic and African Americans in Study 1, which runs somewhat contrary to findings from the school-based survey literature. Rojas et al. (2008) then compared scores on the CRAFFT between consenting conditions. The CRAFFT is a six-item screening that can be rapidly administered and has good sensitivity and specificity in predicting substance use disorders at two positive responses (Knight, Sherritt, Harris, Gates, & Chang, 2003). CRAFFT scores were found to be lower for the active consenting condition and given the low threshold to prompt additional assessment and intervention; these differences were thought to be clinically significant.

#### 4. Summary

Adolescents appear to be legally able to independently consent to participate in research evaluating the outcomes of substance abuse treatment. Furthermore, there are concerns about adolescents' participation rates, representativeness of samples, and reports of risk behaviors when active parental consent is required. Such studies are common in school-based survey research, and efforts to directly estimate differences between consenting conditions for adolescents in clinical outcome studies are rare. These findings support the need to examine the current status quo regarding the collection of parental consent in substance abuse treatment outcome studies and careful consideration of how current parental consenting procedures may be influencing the generalizability of this research. In the remainder of this article, we systematically review the parental consenting procedures of all identified adolescent substance abuse treatment outcome studies and provide recommendations based on these findings.

#### 5. Consenting practices in adolescent substance abuse treatment outcome studies

##### 5.1. Study selection criteria and review procedures

We searched for all available adolescent substance abuse outcome studies published through 2007 by using multiple electronic databases, consulting published meta-analyses (Becker & Curry, 2008; Waldron & Turner, 2008; Williams & Chang, 2000), and contacting authors who are currently conducting such trials or meta-analyses. We reviewed all substance abuse treatment outcome studies conducted in the

United States if (a) at least a portion of the sample included adolescent participants aged 12 to 17 years, (b) participants received substance abuse treatment or were enrolled in a control condition, (c) the study prospectively evaluated posttreatment substance use outcomes, (d) the study did not use secondary analysis with previously collected data, (e) and the study was not a second report based on the same study sample (i.e., long-term findings vs. preliminary findings). We did not exclude studies using nonrandomized designs or that failed to exhibit other signs of methodological rigor (i.e., use of treatment manuals, reported randomization procedures, low attrition; Becker & Curry, 2008) because using these criteria would have reduced the pool of available studies. We did, however, exclude prevention trials and studies on tobacco treatment outcomes. Table 1 presents an overview of the studies (i.e., sample size, treatment conditions, year of publication) included in the review.

Once studies were identified as meeting the inclusion criteria for this review ( $n = 34$ ), we examined each study's method section to determine and code the parental consenting procedures used in the study (1 = active parental consent, 2 = passive parental consent, 3 = not specified). In the event that the data were missing from the article, we contacted the authors directly to collect these data. We analyzed the frequencies (% ,  $n$ ) of studies requiring (and reporting in their articles) parental consent as a condition of treatment participation.

##### 5.2. Parental consenting procedures

Of the 34 studies we reviewed, 14 (41.2%) did provide any information on what parental consenting procedures were used, and for other studies, we could not code consenting procedures as active or passive with available information. We were able to obtain the needed information for exactly half of the studies that did not originally report consenting, as some authors did not reply, did not remember study procedures, or were deceased.

In all but 3 of the 27 studies (89%) for which we had information on consenting procedures, parental consent was required for adolescent participation. So what may have differentiated these 3 studies that did not require parental consent? For one such study, the authors indicated that although they pursued parental consent for all adolescents, they could include adolescent participants older than 13 years in the study due to these adolescents' legal right to consent to treatment. In the second study in which parental consent was not a requirement, the sample consisted of homeless adolescents, only obtaining consent from youth who had recent contact with their parents (Peterson, Baer, Wells, Ginzler, & Garrett, 2006). That is, these authors received a *partial waiver of parental consent* that only applied to some adolescents in the study. Both of these studies involved randomization to treatment condition. Finally, the third study where active parental consent was not required involved youth in state custody, with state authorities providing

Table 1  
Characteristics of studies selected for review

Study	Sample size, <i>N</i>	Age ( <i>M</i> ( <i>SD</i> ) or range)	% minority	Treatments provided	Random sample
Amini et al., 1982	87	16.1 (1.0)	48	I, O	Yes
Azrin et al., 1994	26	13–18	19	BT, OGT	Yes
Azrin et al., 2001	56	15.4 (N/R)	21	ICT, FBT	Yes
Battjes et al., 2004	194	14–18	29	GBT + MI	No
Deas et al., 2000	10	16.6 (0.52)	20	Sertraline + OGT, placebo + OGT	Yes
Dennis et al., 2004	600	15–16	39	(1) MET + CBT5, (2) MET + CBT12, (3) FSN, (4) ACRA, (5) MDFT	Yes
Deskovitz et al., 2004	100	13–17	N/R	PFCP	No
Friedman et al., 1986	130	16–18	25	DTC, O	No
Friedman et al., 1989	135	14–21	10.2	OFT, OGT	Yes
Geller et al., 1998	25	12–18	0	O + lithium, O + placebo	Yes
Grenier et al., 1985	144	9–21	N/R	AA, OFT	No
Godley et al., 2002	114	12–18	26.5	UCC, ACC	Yes
Henggeler et al., 2002	118	12–17	53	MST	Yes
Henggeler et al., 2006	161	12–17	69	UCS, DC + UCS, DC + MST, DC + MST (ECM)	Yes
Iverson et al., 1980	64	8–18	0	JIP	Yes
Joanning et al., 1992	82	11–20	32	FST, AGT, FDE	Yes
Kaminer et al., 1998	32	13–18	11.2	CBT, IT	Yes
Kaminer et al., 2002	88	13–18	21	CBT, PET	Yes
Latimer et al., 2003	43	12–18	19	IFCBT, PET	
Lewis et al., 1990	84	12–22	N/R	PBFT, TIPS	Yes
Liddle et al., 2001	182	13–18	49	MDFT, OGT, MEI	Yes
Liddle et al., 2004	80	11–15	97	MDFT	Yes
Morrall et al., 2004	449	13–17	73	RT	No
Najavits et al., 2006	33	16 (1.22)	21.2	SS	Yes
Peterson et al., 2006	285	14–19	27.7	MET	Yes
Riggs et al., 2004	69	13–19	29.5	Pemoline, placebo	Yes
Ruiz et al., 2005	523	15.8 (1.1)	41	O	Yes
Santisteban et al., 2003	126	12–18	100	BSFT	Yes
Sealock et al., 1997	700	N/R	N/R	RT	No
Slesnick et al., 2007	124	12–17	54	EBFT	Yes
Smith et al., 2006	98	12–18	24	SOFT, 7C	Yes
Szapocznik et al., 1983	37	12–20	100	CFT, OPFT	Yes
Tomlinson et al., 2004	197	15.7 (1.24)	21	RT	No
Waldron et al., 2001	120	13–17	61.6	CBT, OFT, OIFT, OGT	Yes
Winters et al., 2000	245	12–18	15	RT, O	No

Note. 7C = seven challenges; ACC = assertive continuing care; ACRA = Adolescent Community Reinforcement Approach; AA = Alcoholics Anonymous; AGT = adolescent group therapy; BSFT = brief strategic family therapy; BT = behavioral treatment; CBT = cognitive-behavioral therapy; CFT = conjoint family therapy; DC = drug court; DTC = day treatment center; EBFT = ecologically based family therapy; FBT = family behavioral therapy; FDE = family drug education; FSN = family support network; FST = family systems therapy; GBT = group-based treatment; I = inpatient; ICT = individual cognitive therapy; IFCBT = integrated family and cognitive-behavioral therapy; IT = interactional treatment; JIP = Juvenile Intervention Project; MDFT = multidimensional family therapy; MEI = multifamily education intervention; MET = motivational enhancement therapy; MI = motivational interviewing; MST (ECM) = multisystemic therapy (enhanced with cognitive management); N/R = not reported; O = outpatient (unspecified); OFT = other family therapy; OGT = other group therapy; OIFT = other individual and family therapy; OPFT = one person family therapy; PBFT = Purdue brief family therapy; PET = psychoeducational therapy; PFCP = Pathway Family Center Program; RT = residential treatment; SOFT = strengths oriented family therapy; SS = seeking safety; TIPS = training in parenting skills; UCC = usual continuing care; UCS = usual community service.

consent (Morrall, McCaffrey, & Ridgeway, 2004). However, parents were sent a letter and were allowed to withdraw their adolescents if they objected to their participation.

## 6. Discussion and research recommendations

### 6.1. Are adolescent outcomes researchers pursuing parental consent waivers?

Many health services researchers in the substance abuse field will hardly be surprised with the findings of this review. As we mentioned earlier, most IRBs require parental consent

for all adolescent research (Mammel & Kaplan, 1995). However, what is interesting is that given the apparent legal sanction to obtain waivers, and findings from school-based adolescent risk behavior studies, it appears that very few researchers in this area seem able to successfully obtain parental consent waivers. Adolescent outcome researchers may be hesitant to apply to parental consent waivers simply to bypass longer human subject's reviews, which would delay study implementation. It may also be that researchers do not want to bear additional legal risks associated with conducting a study where parental consent was waived. Research is sorely needed, however, to determine whether

any lawsuits have been filed due to adolescent participation in substance abuse treatment or treatment research without parental consent. Brody and Waldron (2000) also note that it makes little sense for a study involving a family-based treatment to obtain a parental consent waiver because parental participation is needed in at least one treatment condition. Exactly 50% of the studies we reviewed involved one or more family-based treatments for adolescent substance abuse. Finally, medication development for adolescents with substance use disorders is an emerging area, and it seems hard to fathom that these outcome studies would be classified as minimal risk studies. About 9% of the studies we reviewed here investigated pharmacological interventions. Besides safety issues, medications are not typically available in community settings where adolescents have the right to independently receive treatments (45 CFR § 46.406(b)), so it is questionable at best to waive parental consent requirements on the grounds that adolescents may consent to their own treatment. Nevertheless, given our limited knowledge about whether adolescent substance abuse treatment researchers are seeking parental consent waivers, additional studies should clarify this while also examining reasons researchers did or did not pursue them.

It also seems that those studies where adolescents may receive family-based treatments should consider the possibility that adolescents may not participate in research due to the possibility of receiving a family-based treatment. Additionally, they may investigate whether parents may coerce their adolescent children to participate. Alternatively, if parents frequently refuse to participate and provide consent for their teen's participation due to the prospect of receiving family treatment, it may be that some self-selection biases are introduced that randomization cannot fix. Anecdotally, we have seen both adolescents and parents refuse study participation due to the prospect of randomization to family treatment (Smith et al., 2006), but future research is needed to investigate whether we should truly be concerned. There is also some evidence that may indicate that teens may feel some pressure to participate in research activities due to parental involvement (Garner, Passetti, Orndorff, & Godley, 2007). When teens were asked about why they continued to participate in substance abuse treatment research follow-up interviews, 5% of teens cited that their "parents would not let me drop out," and 21% said their "parents wanted me to participate." On the other hand, parental encouragement of attending follow-up interviews may simply reflect effective parenting that teaches these adolescents to honor their commitments to research participation. Existing studies do not inform us about the motivations of these parents that drove their encouragement of their teens' ongoing participation, and it seems logical that parental expectancies for research participation should be examined more closely because they could introduce coercion into adolescent research participation decisions and systematic bias in findings. That is, it is entirely possible that teens whose parents want them

to participate, and thus can easily obtain parental consent to do so, have different characteristics from teens whose parents are indifferent toward research participation or unavailable to provide consent.

## 6.2. Suggestions for future research on the impact of parental consenting procedures

Does this nearly universal requirement of parental consent for adolescent participation in substance abuse treatment outcome studies impact the generalizability of our existing findings? The short answer is that we do not know. There are no well-designed empirical studies providing direct evidence that inform us as to what the influence of requiring parental consent may be. However, some school-based survey studies and one screening and brief intervention study found lower estimates of substance use and other indications that samples were not representative of the populations of adolescents to which we want to generalize. Thus, we believe that well-designed studies that can estimate these effects in substance abuse treatment outcome study contexts are sorely needed.

There will be several methodological challenges to conducting such work. First, the biggest challenge to truly answering this question is justifying a design in which parental consenting procedures could be manipulated as study conditions. The only study closely linked to substance abuse outcome studies evaluating the impact of parental consenting procedures was largely accidental in that it was only possible due to a consent waiver not being granted in a second study with a similar clinical protocol as a prior study (Rojas et al., 2008). Naturalistic experiments have many limitations because other factors may better account for sampling biases and risk reporting such as research assistants' interviewing and recruiting skills, the specific procedures in the recruitment protocol (Scott, 2004), or the amount of study compensation, which would need to be held constant. These limitations, along with inadequate reporting of the needed variables discussed below, would also limit findings from meta-analytic studies investigating the association of parental consenting with sample composition and risk reporting. Second, some consideration should be given to expected counts of minority participants, as sample compositions are somewhat determined by regional differences in minority populations and the percentage of clients referred from criminal justice settings in which ethnic minorities are disproportionately represented. Finally, ethical issues exist regarding whether baseline data for youth who decline participation can be accessed to compare their characteristics to those that do consent to study participation. In our previous work with adolescents, we approached this by collecting two separate consents, one for the initial assessment and a separate consent for participation in a longitudinal trial (Smith et al., 2006). Studies comparing participants to nonparticipants, however, may be a reasonable starting point in situations where comparisons could be

made between youth who list parental involvement as a deterrent to participation and those that do not.

The most rigorous, albeit controversial, solution would be to conduct a study that involves prospectively assessing and inviting adolescents into a nonexistent outcome trial while manipulating the parental consenting requirement. Such a design has the advantages of controlling for other factors mentioned above that should be held constant and also circumvents the problem of being unable to use the baseline data of nonparticipants who have already consented to an assessment that may be used for research purposes. However, given the current atmosphere of public distrust in clinical research (NIH Director's Council of Public Representatives, 2005), which is especially salient among ethnic minorities (Corbie-Smith, Thomas, & St. George, 2002), studies using deception would be hard to justify. At present, designs comparing participants to nonparticipants within individual studies and meta-analytic reviews appear more feasible.

In short, we are advocating for additional empirical studies that consider the impact of collecting parental consent on participation rates, sample composition, and baseline reports of substance use and other risk behaviors. We believe that the findings from the broader adolescent risk behavior literature should compel adolescent substance abuse treatment researchers to consider the potential impact of the nearly universal requirement of parental consent for adolescent participation in outcome studies. We discuss one such barrier, inadequate reporting, in the next section.

### 6.3. Reporting parental consenting procedures and reasons for declining participation

One disappointing yet common finding (Spath, Greenberg, & Turrisi, 2008) in systematic reviews is that outcome study publications are often not transparent in their communication of study procedures. Among the studies we reviewed, we find that parental consenting procedures, sample demographic characteristics, and participation rates were not adequately reported. In keeping with the ideals of the CONSORT statement (Moher, Schulz, Altman, & for the CONSORT Group, 2001), which outlines standards for increasing transparent reporting, we think that such explicit statements are needed in all adolescent substance abuse treatment outcome studies. Specifically, the CONSORT statement advocates the use of a detailed flowchart to show readers the inclusion of participants from recruitment through the data analysis. That is, researchers report how many participants met eligibility criteria, were randomized to treatment condition, and ultimately were considered in the analysis. One aspect of the CONSORT's flowchart with special relevance to adolescent treatment researchers is a dedicated space for inserting the number of participants that were excluded for various reasons. We feel it is important for adolescent researchers to rigorously track the number of participants excluded from clinical trials due to inability to collect parental consent. It is our hope that more transparent

reporting on consenting procedures, sample composition, and demographic characteristics would enable future studies on the association between consenting procedures and these variables, which may ultimately increase our knowledge about the impact of the unspoken rule requiring the collection of parental consent.

## 7. Conclusion and recommendations

We discovered that requiring parental consent is the norm in adolescent substance abuse treatment outcome studies despite the apparent ability of researchers in this area to pursue consent waivers if teens can consent to their own treatment in their jurisdictions. It is unclear what factors (i.e., anticipating difficult IRB applications, providing family treatments) are influencing the near universal collection of parental consent and how often researchers in this area have pursued parental consent waivers. We are advocating that adolescent substance abuse treatment researchers study the influence of parental consenting procedures and strive to make published outcome study reports more transparent regarding consenting procedures. Such advances may ultimately inform our interpretation of the current evidence base for adolescent treatments and guide future study designs in our pursuit of improving treatments for adolescent populations.

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