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Original article

The Effects of Requiring Parental Consent for Research on Adolescents' Risk Behaviors: A Meta-analysis

Chao Liu, M.A. [a,*], Ronald B. Cox Jr., Ph.D. [a], Isaac J. Washburn, Ph.D. [a], Julie M. Croff, Ph.D. [b], and Hugh C. Crethar, Ph.D. [b]

[a] *Department of Human Development and Family Science, Oklahoma State University, Stillwater, Oklahoma*
[b] *School of Applied Health and Educational Psychology, Oklahoma State University, Stillwater, Oklahoma*

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A B S T R A C T

Purpose: Requiring parental consent may result in sampling biases that confound scientific conclusions and stifle the representation of children most at risk for adverse outcomes. This study aims to investigate whether active parental consent, compared with passive parental consent, creates a bias in response rate, demographic makeup, and adverse outcomes in adolescent samples.

Methods: A meta-analysis was performed on peer-reviewed articles and unpublished dissertations from 1975 to 2016 in five computerized databases ERIC, PsycINFO, MEDLINE, PubMed and ProQuest. Quantitative studies were retained if they included the following keywords: active consent (or informed consent or parental consent), passive consent (or waiver of consent), risk behavior, adolescen*.

Results: Fifteen studies were identified with a total number of 104,074 children. Results showed (1) response rates were significantly lower for studies using active consent procedure than those using passive consent procedure ($Z = 3.05$, $p = .002$); (2) more females, younger participants, and less African-Americans were included in studies using active consent procedures than studies using passive procedures ($Z = -2.73$, $p = .006$; $Z = -12.06$, $p < .00001$; $Z = 2.19$, $p = .03$, respectively); (3) studies with passive consent procedures showed higher rates of self-reported substance use than studies using active consent procedures ($Z = 3.07$, $p = .002$).

Conclusions: Requiring active parental consent can lead to a systematic bias in the sample where the population under study is misrepresented. Institutional review board committees should collaborate with researchers to find solutions that protect minors without silencing the voice of high-risk youth in the literature.

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IMPLICATIONS AND CONTRIBUTION

Selection biases can result from requiring parental consent when studying adolescents' risk behaviors related to substance use, limiting the generalizability of research findings. Alternative consent procedures such as passive parental consent may be used when research involves substance use behaviors among adolescents.

Parental informed consent is an established federal regulation for protecting minors from potential harms or risks introduced by research. These procedures ensure that parents or guardians are given adequate information about the purpose, benefits, and risks associated with a research study to make an informed decision about their child's participation. The U.S. Department of Health and Human Services (HHS) regulations at Code of Federal Regulations 46.116 state that "no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally

Conflicts of Interest: The authors have no conflicts of interest to disclose.

* Address correspondence to: Chao Liu, M.A., Department of Human Development and Family Science, Oklahoma State University, Stillwater, OK 74075.
E-mail address: chao.liu@okstate.edu (C. Liu).

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authorized representative." However, these regulations also acknowledge that under some circumstances an institutional review board (IRB) may approve a consent procedure that waives or alters parts of this requirement [1]. Although not formally designated in HHS regulations, researchers in practice often refer to two forms of parental consent procedures: active and passive. In "active consent" parents must be informed of the research and provide their permission before a minor child is allowed to participate in any aspect of the research project. "Passive consent" procedures generally describe situations in which the requirement for written permission is waived unless a parent restricts their child's participation via the opt out method specified by the researcher. Under passive consent procedures, parental nonresponse is considered as a permission to participate in the research study.

Potential biases of active consent procedure

The U.S. Department of Education, IRBs, and local school boards have increasingly required more stringent active consent procedures as the result of environmental and statutory changes. A gradual trend toward requiring active parental consent has been observed in 1995 when the House passed the Family Privacy Act that sought to require active parental consent for any government-funded program or activity. Although this Act failed to pass in the Senate, similar provisions were passed in five states (California, Indiana, Kansas, Michigan, and Texas) with several other states putting it under consideration [2]. The increasing preference of active consent over passive consent among school administrators echoes these regulatory changes, probably reflecting a "free of troubles" line of thought. For example, although DHS regulations allow waiving parental consents under certain conditions such as the case that the waiver will not adversely affect the rights and welfare of the child participating in the research or the situation when research could not be practicably carried out without a waiver of parent permission, studies meeting these conditions that have been granted a waiver of parental consent are very limited [3]. When requirements for consent become more stringent, however, science runs the risk of losing the very subjects that are the target of their investigation or intervention [4] and of stifling the voice of those most in need of answers. For example, requiring parental consent may jeopardize the opportunity to conduct research on risk behaviors that begin in adolescence such as suicide, sexually transmitted diseases, pregnancy, and substance use which are the major causes of morbidity and mortality during this period of time [5,6].

Several potential problems may arise from following an active consent procedure, not the least of which is a low response rate. Previous research has reported response rates using active consent ranging from 29% to 60% [7–11], much lower than the response rates of 79%–100% under passive consent procedures [7–9,12–14]. Although various retrieval methods and delivery strategies can boost the response rate under active consent procedure, these practices are often labor intensive and costly. For example, Ellickson and Hawes [7] made intensive follow-up efforts to improve parental consent rates by 52%, but the high cost of the procedures significantly reduced the size of the study the authors were able to conduct.

A low response rate arising from active consent procedures could compromise the validity of research findings due to the introduction of sampling biases. Sampling bias results from nonrandom selection into a study. The low-response rates reported in active consent studies reflect a systematic bias of sampling in a way that over-represents some portions of the population while under-representing others. For example, active consent procedures yielded study samples that over-represented female and Caucasian students [15,16] and students with high academic achievement [10], and under-represented minority groups such as African-American and Asian American students, Hispanic youth [9,17], children who were low achievers, and children whose parents were less well-educated [15,16].

Significant differences between respondents and non-respondents may also emerge in the prevalence of risk behaviors when active consent procedures are used [12,17]. For example, Severson and Ary [18] reported a significantly higher number of risk behaviors (e.g., smoke tobacco, marijuana, and drink alcohol) reported by students whose parents did not provide consent compared to students with consenting parents.

Estimates of prevalence rates may also be affected by an interaction between consent procedures and subject characteristics. For example, age of the student has also been found to influence self-report of some risk behaviors between samples requiring parental consent versus those that do not. Requiring written parental consent significantly reduced self-report of smoking among ninth grade students when compared with a sample in the same grade not requiring written parental consent, although this difference disappeared among 12th grade students [15].

Counterargument to biases of active consent procedure

Notwithstanding the problems associated with active consent procedures, others debate the extent and significance of the bias. For example, Dent, Sussman, and Stacy [19] examined the differences between a full school-based sample and subsamples restricted by the requirement of active parental consent on several outcomes of a substance use survey. Little or no bias was found on measures related to mental health, drug use, or violence, despite some small differences in demographic variables. And although males and African-American students were under-represented in the sample, behavioral outcomes and mental health indicators were generally unaffected by the consent format (i.e., within statistical sampling error). Similarly, in another study [15] where a sensitive health survey was used to examine the impact of the active consent procedure, the authors found no significant differences between active and passive consent groups for self-report of alcohol or illicit drug use although several demographic differences (e.g., ethnicity and family structure) still existed.

Given these inconsistencies, this study aims to systematically examine the role of parental consent in research involving risk behaviors among adolescents by conducting a meta-analysis on studies that compared an active parental consent procedure with a passive parental consent procedure. Specifically, we examine whether an active consent procedure leads to differences in response rate, demographic characteristics, and estimates of substance use and non–substance use risk behaviors among adolescents.

Methods

Selection of studies

The following steps guided our approach to locate studies and to maximize the chance of including all relevant studies. First, we

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