Published in final edited form as:
J Empir Res Hum Res Ethics. 2010 June ; 5(2): 57–64. doi:10.1525/jer.2010.5.2.57.

Parental Permission and Perceived Research Benefits in Adolescent STI Research

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Abstract

AN UNDERSTANDING OF WHY PARENTS provide consent for adolescent participation in research on sensitive topics can inform and improve the ethical conduct and review of such research. As part of a longitudinal study of sexually transmitted infections (STIs) in lower-income adolescents, we asked 134 parents why they permitted their daughter to participate, analyzing responses using qualitative methods. Over half described participation benefits, providing reasons such as the study being generally good for their daughters, sex education, someone to talk to, and STI testing. Other reasons included positive interactions and familiarity with research and clinical staff, friend or family member participation, and adolescent autonomy in making the decision to participate. If parents perceived their daughter to be "at risk" in some way, such as for STI or pregnancy, they were more likely to cite participation benefits. These data can be used to make such research more sensitive to family and community needs.

Keywords

bioethics; adolescent; sexually transmitted diseases; parental consent; qualitative research; research ethics

THIS STUDY EXAMINES REASONS that parents consent to adolescent participation in longitudinal behavioral research on sexually transmitted infections (STI). We focus on parent perceptions of risk and benefit. In behavioral research, benefits and harms are difficult to quantify, and few investigators have systematically examined the perceptions and experiences of benefits and harms of behavioral research (Sieber, 2004), particularly research on sensitive topics with vulnerable populations (Sieber & Stanley, 1988). Yet information on how parents perceive adolescent participation in behavioral research is critical to the ethical design, review, and conduct of this type of research.

A favorable risk-benefit ratio is a requirement for ethical research (Emanuel, Wendler, & Grady, 2000). This ethical tenet embodies the principles of beneficence and respect for persons (Department of Health, Education, and Welfare, 1979), and is codified in the NIH "Common Rule" governing ethical review of research (Department of Health & Human Services, 2005a). Under federal regulations, adolescents who have not attained the legal age to consent to medical procedures involved in the research are classified as children, and as

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Author Contributions. Dr. Ott led the development, data analysis, and writing of this manuscript. Mr. Rosenberger participated in data analysis and writing of this manuscript. Dr. Fortenberry was responsible for the design and data collection of the larger study, and contributed to data analysis and review of the manuscript.

such, are members of a vulnerable population deserving of special protections with increased scrutiny of potential harms and benefits (Department of Health & Human Services, 2005b). Parental permission is a safeguard in research with children, in that it is assumed that parents will weigh risks and benefits, and make a decision in the best interest of their child. While regulations focus on participation of children in research that carries the potential for direct benefit to the child (e.g., clinical trials or therapeutic research), regulations allow for research that does not carry direct medical benefit, but is low risk (Department of Health & Human Services, 2005b). This determination of risk and benefit for research with adolescents is generally done by investigators and institutional review boards, and rarely are parents' perceptions of risk considered.

Our knowledge of parents' perceptions of research risks and benefits for their adolescents comes primarily from biomedical research protocols. Reasonably well described are parents' perceived benefits and reasons for permitting adolescent participation in asthma research (Brody et al., 2005; Rothmier, Lasley, & Shapiro, 2003) and oncology clinical trials (Read et al., 2009). However, these studies focus on therapeutic research among populations with disease; less is known about parental permission for research with well, community-based samples.

Existing data on parental permission for adolescent participation in behavioral research and non-beneficial medical research comes primarily from hypothetical research studies (Annett et al., 2004; Brody et al., 2006; Fisher & Wallace, 2000; Fisher, 2003). Findings from these hypothetical studies have had important implications for the ethical review of adolescent research. One example is that parents, adolescents, and pediatricians perceived different levels of risks and benefits for the same non-beneficial asthma research protocols, suggesting that it is important to involve parents and adolescents in the initial ethical review of such protocols (Annett et al., 2004). A second example is that parent participants evaluating hypothetical studies of youth drug use recognized that adolescents were more likely to answer surveys truthfully if parents were unaware of their participation, suggesting that parents are aware of ethical tensions between respecting parental rights and adolescents' evolving decisional capacity (Fisher, 2003). All of these studies are limited in that parents are not asked to provide permission for adolescent participation in actual research. Just as intention is an imperfect predictor of behavior, parental reasoning in a hypothetical situation may not reflect decision-making in the actual research situation.

Over the past decade, behavioral research protocols have become increasingly more complex, introducing higher burdens for participants and potential new risks for confidentiality and disclosure. Thus empirical data on perceived risks and benefits become more important. As part of an intensive longitudinal study of STI among adolescent women 14 to 17 years old, we asked a subset of their parents their reasons for permitting their daughter to participate, and analyzed their responses using qualitative methods.

Methods

Larger Longitudinal Study—The Young Women's Project

As part of a longitudinal cohort study of risk and protective factors for STI, adolescent women, 14 to 17 years old, were enrolled from community primary care clinics serving low- and middle-income urban communities with high rates of STIs. Recruitment occurred over several years, and participants could be recruited directly from the community clinics or were self-referred. Sexual experience was not an inclusion criterion. Each adolescent provided written consent and parents provided written permission. The study was approved by the Institutional Review Board (IRB) of Indiana University Purdue University at Indianapolis–Clarian. Because adolescents can consent to STI testing and treatment in

Indiana (as for all states), investigators could have requested a waiver of parental permission (see the Society for Adolescent Medicine position paper for a discussion of this issue [Santelli et al., 2003]). Because the longitudinal and intensive nature of this study would have benefited from parent knowledge and support, investigators did not request a waiver of parent permission.

The initial study period was 27 months. The study protocol asked the following from adolescent participants: (1) a physical exam once per year, including a pelvic exam; (2) face-to-face interviews four times per year (one with the physical exam); (3) two 3-month periods of daily diaries twice a year, with diaries collected weekly by a trained research assistant; and (4) self-collected vaginal swabs for STI testing to be done at all clinic visits and during the weekly pick-up during diary collection periods, for a total of 24 to 28 swabs per year. The face-to-face interviews inquired about romantic partners, sexual behaviors, and a range of other risk factors and protective influences. Participants were reimbursed $20 per interview, $2 per diary, and $5 per vaginal swab, with bonuses for completing more than 80% of requested diaries and tests. These amounts were based upon time and typical adolescent wages for unskilled labor (Dickert & Grady, 1999), and consistent with other adolescent protocols (Borzekowski et al., 2003). (For additional details of the study procedures, see Fortenberry et al., 2005.) The only direct medical benefit was frequent STI screening. A formal educational curriculum was not a part of the study. However, during the course of the study, field staff answered all questions, provided targeted information when appropriate (e.g., standard of care information about STIs and risk reduction when an STI was diagnosed), and provided referrals when needed (e.g., for contraceptive services or domestic violence).

The informed consent statement included the following elements: (1) statement of study purpose, focusing on why it was important to screen asymptomatic individuals for STIs; (2) procedures for the study as listed above; (3) risks of participating in the study, including blood draws, pelvic exams, and anxiety about answering questions about sexual behavior; (4) costs of participating in the study; (5) confidentiality procedures; (6) contact information; (7) payments; (8) statement that participants will be informed of new findings, and (9) instructions to call the principal investigators with any questions about the research project, and to contact the IRB if they are unable to contact the PI, are dissatisfied with the PI’s response, or have concerns about the study.

Participants—Parental Consent Sub-Study

After the consent process for the larger study, 134 parents or guardians (hereafter referred to as “parents”) were asked to complete a brief interviewer-administered survey. In four cases, a parent had two daughters enrolling in the study, and filled out two surveys. We used only one survey per family (in all four cases, the two responses to the question about reasons for parent consent were nearly identical). Twelve surveys were missing the reason for parent consent on an otherwise complete parent survey, and it was unclear whether the question was not asked, or the parents declined to answer. We included these twelve surveys in our analysis as “no response.” We used a convenience sample, meaning that, if time, clinic space, and study personnel were available to administer the parent survey, all eligible parents and guardians were invited to participate (134/387). There were no direct refusals, however, because of the complex and lengthy study procedures, and because the recruitment occurred in a very busy afternoon adolescent clinic, time, space, and personnel were common limitations.

Study Procedures

The parent survey was administered at the end of the recruitment process, in the clinic. The study had been explained, the adolescent and parent provided written informed consent to participate, and arrangements for the first study visit had been made. The parent survey included an open-ended question, "What led you to consent to participation in this study?" Project staff wrote down the parents' responses, often summarizing rather than writing verbatim. Responses were generally one to four sentences long. Textual data were entered into a Microsoft Excel database.

Qualitative Analysis

We used a content analysis approach to identify key reasons for permission for research participation, as well as key influences on permission (Neuendorf, 2002). Textual data were initially open-coded by two authors (MO & JR), identifying and categorizing reasons for participation and related influences. Open coding is a dynamic, interactive process in which authors read selections of data, inductively generate themes or topics from the data, apply to subsequently read data, and revise in an iterative process. Inter-rater reliability coefficients are typically not calculated because the raters are not independent. Initial codes were compared to subsequently read data. Similar codes were collapsed, and differences were resolved by discussion. For each reason or influence, authors developed a list of its properties and dimensions (Strauss & Corbin, 1998).

Authors identified nine different reasons given for participation, which fit into four broad themes. Parents could provide more than one reason for participation; in these cases, both reasons were coded. We identified one important influence on permission, parents perceiving their daughter to be "at risk" in some way (for example, at risk for pregnancy or at risk for STIs). As part of the analysis, we compared responses from parents who indicated that their child was at risk to those who did not indicate that their adolescent was at risk. We used chisquare statistics to examine associations between perceiving an adolescent to be "at risk" and reasons for participation.

Results

Participants

Parents and guardians included 114 females, 6 males, and 10 who did not indicate their gender. Ages ranged from 28 to 83 years, and ethnicities included African American (96), White (19), Latino (1), and those who did not indicate an ethnicity (14).

REASONS FOR PARTICIPATION—Parents and guardians provided nine key reasons for permitting their adolescent to participate in an intensive longitudinal study of risk and protective factors for STI. We grouped these nine reasons into four broad themes: (1) participation benefits (i.e., the study would be good for the adolescent), (2) relationships and familiarity with staff, (3) adolescent autonomy, and (4) other reasons. "Other reasons" included altruism and payments, and were included because they were described in literature or reflect commonly held lay perceptions. Broad themes, reasons for participation, example responses, and the frequency of those responses can be found in Table 1.

Over half (n = 75) of the parents and guardians described participation benefits, indicating that participation would be good for the adolescent in some way. Most of those (n = 42) responses were general or non-specific about the ways the study might benefit their adolescent. Many (n = 32) also perceived that their adolescent would receive health education as a result of participation. Types of education mentioned included education about STIs, contraception, and decision-making about sex. Nine parents responded that the

study might provide the adolescent with someone to "talk to." This someone could be a peer, physician, or project staff, although several (n = 3) did not name a person, but rather stated that the study would provide a chance for the adolescent to "talk openly." Only eight parents specifically mentioned STI testing as a reason for study participation.

The second most common response from parents and guardians related to adolescent autonomy, with the parents stating that the adolescent herself wanted to participate (n = 30). These parents clearly indicated that it was the adolescent making the choice to participate.

The third most common theme centered around relationships and familiarity with both clinic and research staff (n = 23). Fourteen parents or guardians said that they allowed participation because another family member (sister, cousin), a friend of the family, or a friend of the adolescent was already participating in the study. Nine parents responded by citing a positive interaction with research staff (project director or research assistant) or encouragement by clinic staff.

Finally, a minority of parents gave other reasons for permitting study participation. Five parents said that they allowed participation because of financial reimbursement, and one parent gave an altruistic reason. Two parents stated "no reason" or "no comment."

Risk

Although parents were not specifically asked whether they perceived their adolescent to be "at risk," 22 (17%) spontaneously identified their adolescent to be at risk in some way, and linked that risk to their reasons for participation. Parents referenced the following risks: (1) behavioral risks, such as early sexual activity or multiple partners; (2) past history of, or current risk for STIs; (3) risk for pregnancy; (4) poor knowledge of contraception and STI prevention; or (5) generally "at risk." Parents and guardians who perceived their adolescent to be at risk in one of these ways were more likely to describe participation benefits (generally good, provide health education, provide someone to talk to, or provide STI testing) ($\chi^2 = 15.5$, $p < .01$).

Discussion

In granting permission for STI research participation, parents focused on participation benefits of STI research. Many of these participation benefits, such as sexual health education and connections with adult health professionals, were not a part of the study procedures nor mentioned in the consent form. Only a small number of parents mentioned enhanced STI screening, the one direct medical benefit of this study. Few gave reasons conventionally cited in the research literature (or included on consent forms), such as financial or altruistic reasons. Parents' reasons for giving permission to participate in research were related to their perception of their adolescent's risk for STIs, pregnancy, and other poor outcomes.

Differences between Parents and Investigators

These results raise important ethical issues related to our understanding of parental consent, and to differences between investigators' and parents' assessments of benefits and harms. It is possible that the parents' perceptions of benefits were due to misunderstanding the difference between the nature of research versus clinical care, akin to the therapeutic misconception in clinical trials (Horng & Grady, 2003). However, this rests on the assumption that investigators' and IRBs' assessment of research benefits and harms is "correct" and the parents' assessment is "incorrect" (Kimmelman, 2007). Research suggests that assessments of risk and benefit can be influenced by values, culture, contexts, and the nature of the study protocol (Slovic, 1999). Building on this perspective, it is also possible

that the parents are correct in their perception of benefits, but that, compared to investigators and IRB members, parents hold different views of what is "educational," or have different values, culture, or life contexts, leading to a different assessment of risk and benefit. For example, perhaps parents felt that study participation itself was an educational opportunity in that the adolescent would be exposed to STI testing and information about that testing. This view is consistent with other research, in which a multiethnic sample of parents perceived that adolescents might "learn something" from taking a drug or suicide survey (Fisher, 2003).

Contact Benefits and Other Developmental Benefits

Of particular interest is parents' perceptions that contact with professional research staff would be beneficial to their adolescent. This perception is consistent with adolescent health research showing that connection to a caring adult is protective for a variety of behavioral risks (Resnick et al., 1997). For a family living in a resource-poor community, such as those participating in this study, research participation may be one of only a few opportunities for adolescents to have ongoing contact with an engaged professional adult. It raises the issue of developmental benefits, or whether there are benefits that are specific to a particular age or developmental stage. In this case, if research meets adolescents' developmental needs for adult connection, mentors, and role models, this could be considered a developmental benefit.

Vulnerability

Parents' perceptions of adolescents being "at risk," and the different reasons for research participation based upon those perceptions, raise important questions about how parents and investigators determine capacity and vulnerability for adolescents. From a regulatory stand-point, adolescents are designated as a vulnerable group based solely upon whether they have achieved the age to consent to health care services in their state (Department of Health & Human Services, 2005b). However, the parents in this study clearly delineated characteristics of individual adolescents that would enable them to benefit more from the study (i.e., sexually active adolescents with multiple partners getting frequent STI tests).

Newer ethical understandings of vulnerability focus upon characteristics of individuals (i.e., factors influencing capacity to understand and provide voluntary consent), rather than membership in a group (Iltis, 2009; Iltis et al., 2009). Developmental aspects of adolescence directly related to vulnerability and capacity include evolving cognitive skills, life experience, and contextual factors such as poverty and education (Kipnis, 2003). Parents would be well positioned to understand their adolescents' vulnerabilities and capacities from this perspective.

This study has important limitations. First, we did not survey parents who declined participation. By not assessing families who declined, we missed those with concerns about potential research harm, such as loss of confidentiality. Second, only a subset of parents and guardians were surveyed. This was due to time, clinic space, and staffing constraints, but it is not known whether a systematic bias existed. Third, the sample was primarily from one ethnic group, potentially limiting generalizability. Finally, the responses were from a single open-ended question. Research staff did not have the opportunity to ask parents to elaborate on responses (e.g., probes).

Despite these methodological limitations, this study makes four important contributions to our understanding of how parents view the risks and benefits of low-risk, community-based behavioral research with adolescents. First, much empirical research on research ethics uses hypothetical research studies (see, for example, Annett et al. [2004] or Fisher [2003]). These

data were collected as part of an actual longitudinal study, reflecting a "real-life" decision. Second, our understanding of parental consent is derived largely from therapeutic studies with acutely or chronically ill patients (see, for example, Read et al. [2009]). Issues related to vulnerability, potential for benefit, and real and potential harms, are markedly different when adolescents are ill or hospitalized, and illness has been described as a distinct additional type of vulnerability (Kipnis, 2003). Our data help extend this understanding of parental consent to research with healthy populations in community-based settings. Third, existing studies examining ethical aspects of adolescent research participation are conceptualized around single surveys or infrequent longitudinal surveys (e.g., Fisher [2003]). Our data are from an intensive longitudinal study—adolescents completed daily diaries, quarterly surveys, and frequent STD tests, for years. While longitudinal research allows a better understanding of sensitive health behaviors, it can also be burdensome, with few direct benefits to adolescent participants and families. Understanding parent consent for this type of intensive protocol is important, because behavioral research is moving toward longitudinal studies with similarly intensive protocols.

Finally, our study participants were a vulnerable population (female adolescents in a resource-poor setting), and topically, the study examined a sensitive issue (sexual behavior and STDs). This type of research is necessary to inform prevention efforts (Santelli et al., 2003), however, it presents challenges for IRB review. With sensitive topics and vulnerable populations, investigators and IRBs are called upon to make ethical decisions about the balance of benefits, risks, and burdens of these studies based upon minimal empirical data. This study adds to our understanding of how families make decisions to participate in research on a sensitive topic, and points to differences between parents' perceptions of research benefits and those of investigators and IRBs. An improved understanding of research participation can inform the ethical review of behavioral research, making it more responsive to families' needs.

Best Practices

Consistent with other research (Fisher, 2003; Scherer, Annett, & Brody, 2007), the parents in our study provided a distinct and useful perspective on the assessment of risk and benefits. This perspective needs to be represented in both the design and the ethical review of adolescent health research. Best practices for the integration of family perspectives into the IRB's ethical review of research have been discussed by others (see, for example, the Society for Adolescent Medicine Guidelines for Adolescent Health Research [Santelli et al., 2003], or Levine [2008]). Their recommendations range from revising the current regulatory structure to better fit the developmental realities of adolescence (Levine, 2008), to using elements of the existing regulatory structure (e.g. the IRB's "community representatives") to better represent the perspectives of adolescents and parents in the target populations of interest. Our findings also reinforce the need for investigators to follow best practices in adolescent health research. Of particular importance is the recommendation that researchers incorporate parent perspectives into the study design and execution through mechanisms such as community advisory boards (Santelli et al., 2003).

Research agenda

This study raises two specific areas for further research. First, longitudinal research is needed to better understand how perceptions of risk and benefit change over time, and to determine the stability and accuracy of parents' (and adolescents') expectations for and experience of research risk and benefit over time.

Second, the concept of "developmental benefits" of research participation, or benefits that may be unique to adolescents, deserves additional research. Because adolescence is a time of

intense cognitive, social, and emotional development, it is likely that they will experience research participation differently from adults or younger children. Our finding of parent perceptions of "contact benefits," in which research staff act as role models and research participation provides a connection to professional adults, is an example of a developmental benefit.

Educational implications

Currently, risks and benefits for adolescents participating in research on sensitive issues are initially laid out by investigators, and then confirmed or amended by IRBs. This process could be informed by our emerging understanding of how families perceive and experience the risks and benefits of adolescent research. IRBs may want to incorporate this understanding into member education on the evaluation of adolescent protocols.

Acknowledgments

These data were originally presented as a poster at the Pediatric Academic Societies and Asian Society for Pediatric Research Joint Meeting, in Honolulu, Hawaii, on May 4, 2008, E-PAS2008-4478.2 (available at http://www.abstracts2view.com/pas/index.php). The overall Young Women's Project was supported by NIH/NIAID (U19 AI031494-15) and NIH/NICHD (R01 HD 044387). Dr. Ott's time and data analysis were support by NIH/NICHD K23-HD049444-01A2.

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TABLE 1

Reasons for Parent Permission.

Theme	Reasons	N (%)	Sample Responses
Participation Benefits		***75 (58%)***	
	Generally benefcial	42 (32%)	• Mom feels subject could beneft from the study. This also serves as an outlet for the girls to express themselves.
	Health education	32 (25%)	• Subject was dating three guys at the time of enrollment. Dad wanted subject to have more education on STDs and protection. He thought that this would be a good way for her to get it.
	Contact with adult	9 (7%)	• Mom thought program would be good for daughter to open up and talk freely.
	STI testing	8 (6%)	• Mom thinks subject is sexually active. Mom feels subject will beneft from study by being checked for STI weekly. Mom also feels that subject will open up to our staff.
Relationships/Familiarity with Staff		***23 (18%)***	
	Family member or friend participating	14 (11%)	• Sister in project and encouraged subject to join.
	Positive interaction with project staff or clinicians	9 (7%)	• The lady in the program is very nice and explained everything well. No pressure and gave us time to think about it and read all the papers involving the study.
Adolescent Autonomy	Adolescent chose to participate	***30 (23%)***	• Daughter wanted to, and Mom didn't see any harm in participating.
			• She (daughter) was excited about it.
Other Reasons		***8 (6%)***	
	Financial	5 (4%)	• For the money. Mom states that a lot of time Nakia wants money and she does not have it. Mom thought this would be a good program.
	Altruism	1 (<1%)	
No reason	No reason	***2 (<2%)***	
Missing Responses		12 (9%)	