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Participation of Children in Clinical Research

Factors that Influence a Parent's Decision to Consent

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Background: **Given the initiatives of the National Institutes of Health and other agencies to include children in research, it is important to understand the factors that influence their participation. This study was designed to identify factors that influence parents' decisions to consent to their child's participation in clinical research.**

Methods: **This survey study consisted of 505 parents who had been approached for permission to allow their child to participate in a clinical anesthesia or surgery study at a large tertiary care children's hospital. Regardless of whether the parents consented to (consenters, n = 411), or declined (nonconsenters, n = 94) their child's participation in a study, they were offered the opportunity to complete a questionnaire eliciting information regarding factors that had influenced their decision.**

Results: **Consenters exhibited less uncertainty in their decision making, were more trusting of the medical system, had greater understanding of the research, and believed that the environment in which consent was sought was less pressured than nonconsenters. Predictors of consent included low perceived risk, degree to which the parent read the consent document, characteristics of the consent document, parental understanding, perceived importance of the study, and perceived benefits.**

Conclusions: **Identification of factors that influence parents' decisions to allow their child to participate in a clinical research study will be important by way of developing strategies to improve the manner in which study information is disclosed and to ensure that parents are truly informed.**

THE opportunity for subjects to participate in clinical research satisfies the bioethical concept of justice. This provides for the equitable distribution of both the burdens and the benefits of research to all potential subjects regardless of age, sex, socioeconomic status, race/ethnicity, and health status.[1,2] In addition to satisfying this societal element, participation in a research study is important scientifically as a means to establish a representative sample with adequate statistical power.

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Participation of children in clinical research has become a priority of the National Institutes of Health such that any research protocol submitted for funding is required to justify the exclusion of children.[3,4] However, for a child to participate in clinical research, at least one parent must give permission, and the child, if deemed able to do so, must give his or her assent. The overriding goal of the parent as a surrogate decision maker must be to protect the welfare of the child.[5] As such, it is imperative that parents are given sufficient information to make an informed choice, in an environment conducive to decision making. Because nonparticipation in a research study may introduce a substantial selection bias,[6] it is important to identify the factors that influence a research subject's or their surrogate's decision to consent to or decline participation in clinical research. This study, therefore, was designed to examine factors that influence parents' decisions to allow their children to participate in clinical anesthesia research.

Materials and Methods

The University of Michigan's Institutional Review Board (Ann Arbor, Michigan) approved this study. The study population included 505 parents/guardians who had been approached to allow their child to participate in any one of 18 ongoing clinical anesthesia (n = 15) or surgery (n = 3) studies. The demographics of this population have been described elsewhere,[7] although the data presented are new. Information for each study was presented both verbally and in written format by research nurses, research assistants, and in a few cases by investigators, either on the day(s) before surgery or, in most cases, on the day of surgery. Regardless of whether the parents had consented to allow their child to take part in one of these studies, the parents were given the opportunity to complete a questionnaire regarding factors that had influenced their decision. The parents completed the questionnaires while their child was in surgery or, if they preferred, at home.

The questionnaire was designed to elicit general demographic data regarding the parents, their children, and the researchers. In addition, the questionnaire addressed factors related to (1) the characteristics of the subject, *e.g.*, age, health status, previous experience as a research subject, and understanding of the research; (2) characteristics related to the environment in which consent was sought, *e.g.*, privacy, time allotted for decision making, and perceived pressure/coercion; (3) psycho-

social characteristics, *e.g.*, altruism, trust in the medical system, decisional uncertainty, and understanding; (4) characteristics of the researcher, *e.g.*, hierarchy, demeanor, and demographics; and (5) characteristics of the informed consent information, *e.g.*, clarity and completeness of disclosure. A copy of the questionnaire is available on the ANESTHESIOLOGY Web site at http://www.anesthesiology.org.

In addition to the questionnaire, parents were interviewed to determine their understanding of 11 core elements of disclosure, including the risks, benefits, protocol, purpose, alternatives, and others. Data regarding parental understanding of these elements are presented elsewhere.[7]

In developing the questionnaire, a list of constructs was generated that defined the factors of interest. These constructs were based on previous studies from our department,[8,9] a review of the literature,[10] and expert opinion. After identification of the constructs, an item (question) pool was generated by which the constructs could be defined and measured. Wherever possible, existing items from previously validated tools were used or modified, *e.g.*, the Decisional Conflict Scale[11,12] and the NEO Personality Inventory-Revised[13,14] (NEO PI-R; Psychological Assessment Resources, Odessa, FL). These scales have demonstrated good validity and reliability ($\alpha = 0.78$ and 0.86–0.95, respectively). Each construct was defined by a minimum of three items (see Web Enhancement). Some items were reversed to assess reliability. Responses to items were scored using a five-point Likert scale of strongly disagree (1), disagree (2), neither disagree nor agree (3), agree (4), and strongly agree (5). Pilot testing of the questionnaire occurred in three stages. Questionnaires were first administered to several lay individuals to determine the face validity of the items. Content validity was evaluated by administering the questionnaire to faculty members and research personnel within our department. Items that were considered ambiguous or confusing were reworded or discarded. Finally, questionnaires were administered to a cohort of parents to determine the internal consistency of the items. Internal consistency measures of reliability of the survey items were analyzed by determination of Cronbach (coefficient) alphas. Items with Cronbach alpha values of 0.6 or less (unacceptable reliability) were discarded. The parents' perceptions of the risks, the benefits to their child and to others, the importance of the study, and their anxiety were measured using 0–10 visual analog scales (10 = high). The visual analog scale for anxiety provides a simple and valid measure of global anxiety ($\alpha = 0.61$–0.73).[15,16] The readability of the consent forms for the studies was measured using the Flesch Reading Ease (0–100 scale where 100 = easiest) and Flesch-Kincaid Grade level tests (grade reading level).[17]

Statistical Analysis

Statistical analyses were performed using SPSS® statistical software (SPSS Inc., Chicago, IL). The sample size required to meet the aims of the study was calculated using standard survey methodology. We estimated that there would be approximately 3,000 on-site pediatric surgical cases performed during the study period at the University of Michigan Children's Hospital. Based on this figure, we needed to sample 500 parents/guardians to provide a representative sample with a confidence level of 95% and a confidence interval of ± 4%. Furthermore, because we were also interested in comparing differences in understanding between consenters and nonconsenters, we calculated, based on preliminary data, that we required a minimum of 94 parents per group (90% power).

Descriptive data were analyzed using frequency distributions. Internal consistency measures of reliability of the survey items were analyzed by determination of Cronbach (coefficient) alphas. Cronbach alpha values of 0.7 or greater were considered to represent excellent internal consistency. An exploratory factor analysis was performed to identify underlying factors that explained the variance among sets of items in the questionnaire and to support the scales used in the study. In consultation with an expert in factor analysis, salient factor loadings were selected based on sample size using the approach described by Gorusch.[18] Comparisons of parametric data between consenters and nonconsenters were performed using unpaired *t* tests with Bonferroni corrections for multiple comparisons. Nonparametric comparisons were analyzed using chi-square and Mann–Whitney U tests. Correlation of independent variables with the dependent variable (consent/nonconsent) were analyzed using the Spearman correlation coefficient (rho). Factors that were shown to be significantly associated with the decision to consent were entered into a logistic regression model with backward selection. Data are expressed as percentages, mean ± SD. Based on the number of comparisons and using a Bonferroni correction, significance was accepted at the 0.29% level ($P < 0.0029$).

Results

A total of 569 parents who had been approached to have their child participate in one of 18 clinical studies were invited to complete the questionnaire. Of these, 505 parents completed the questionnaire, including 411 who had consented to allow their child to participate in one of the studies (consenters) and 94 who had declined their child's participation (nonconsenters). The demographics of the study sample are described in table 1. The studies in which the children were approached to participate are described in table 2.

Table 1. Parent and Child Demographics

	Consenters (n = 411)	Nonconsenters (n = 94)	All Parents (n = 505)
Parent's age, yr	37.3 ± 7.4	36.1 ± 6.5	37.1 ± 7.3
Child's age, yr	7.6 ± 4.9†	5.1 ± 4.3	7.2 ± 4.9
Child's health*	8.5 ± 1.7	8.6 ± 1.9	8.5 ± 1.8
Child's sex (M/F), %	57.7/42.3	68.5/31.5	59.7/40.3
Race, No. (%)			
White	355 (89.6)	78 (89.8)	434 (89.6)
African-American	16 (4.0)	6 (6.8)	22 (4.5)
Hispanic	7 (1.8)	0 (0.0)	7 (1.4)
Other	18 (4.5)	3 (3.4)	21 (4.3)
Education level, No. (%)			
≤ High school graduate	107 (26.6)†	13 (14.4)	120 (24.4)
Some college	102 (25.4)	27 (30.0)	129 (26.2)
≥ College graduate	193 (48.0)	50 (55.6)	243 (49.4)
Prior research subject—child	80 (20.0)	17 (18.3)	97 (19.6)
Prior research subject—parent	98 (24.4)	20 (21.5)	118 (23.9)
Therapeutic/nontherapeutic study, %	19.8/80.2†	33.7/66.3	22.3/77.7
Consent day of surgery/day(s) before, %	91.7/8.3	87.5/12.5	91.0/9.0

Data are expressed as mean ± SD or No. (%). Percentages are based on the number of subjects who provided information.

* Based on a 0–10 scale, where 10 = extremely healthy. † $P < 0.05$ *vs.* nonconsenters.

The internal consistency measures of reliability of the items for each construct were calculated for both consenters and nonconsenters. Cronbach alpha values were as follows: decisional uncertainty, 0.69, 0.74 (consenters, nonconsenters, respectively); decisional effectiveness, 0.69, 0.70; trust, 0.61, 0.64; altruism, 0.82, 0.84; quality of informed consent document, 0.73, 0.79; environment, 0.78, 0.82; researcher characteristics, 0.75, 0.71; and understanding, 0.87, 0.83. Comparisons between the two groups with respect to the constructs of interest are described in table 3. Consenters were less uncertain regarding their decisions, believed that the environment was more conducive to decision making (time, pressure, privacy), and felt better about their interactions with the researcher.

Overall, 91% of parents were approached for consent on the day of surgery. All but two or three parents completed the questionnaire while their child was in surgery. The timing of consent, the time taken to disclose information about the study, and the time allotted for the parents to make a decision (average, 25 min) were similar for both consenters and nonconsenters. Similarly, there were no differences between groups with respect to their preferences for making treatment decisions, *i.e.*, paternalistic *versus* shared (parent and doctor) decision making. The degree to which the parents listened to the researcher, read the informed consent document, and understood the information were compared between groups. Consenters were more likely to have listened completely (89.3% *vs.* 67.8%, $P <$

Table 2. Studies for Which Children Were Approached to Participate

Title	Design	IRB Risk
Tramadol for postsurgical pain	RCT	Minor/Minimal
Fenoldopam pharmacodynamics and pharmacokinetics	RCT	Minor/Minimal
Dolasetron for PONV	RCT	Minor/Minimal
Facemask *vs.* induction pacifier device	RCT	Minimal
Glycopyrrolate for URIs	RCT	Minor/Minimal
Aprotinin for craniofacial surgery	RCT	Minor/Minimal
Surgical glue *vs.* stitches for surgical incisions	RCT	Minimal
Esmolol for hemodynamic maintenance	RCT	Minor/Minimal
Surgical incisions for Fontan procedure	RCT	Minor/Minimal
Colloid *vs.* crystalloid for CPB prime	RCT	Minimal
Pain assessment in cognitively impaired	Observational	Minimal
Assessment of pain management practices	Record review/survey	Minimal
Comparison of pulse oximeters	Observational	Minimal
Validation of platelet function test	Blood draw	Minimal
Systolic pressure variation for assessment of fluid status	Observational	Minimal
Rapacuronium evaluation	Observational	Minor/Minimal
MLAC of bupivacaine and ropivacaine	RCT/up–down sequential dosing	Minor/Minimal
BIS and sedation	Observational	Minimal

BIS = Bispectral Index; CPB = cardiopulmonary bypass; IRB = institutional review board; MLAC = minimum local anesthetic concentration; PONV = postoperative nausea and vomiting; RCT = randomized controlled trial; URI = upper respiratory infection.

Table 3. Construct Scores

Construct (No. of Items, Score Range)	Consenters (n = 411)	Nonconsenters (n = 94)	All Parents (n = 505)
Decisional uncertainty (3, 3–15)	6.2 ± 1.9 (6)*	7.2 ± 2.4 (7)	6.4 ± 2.1 (6)
Decisional effectiveness (3, 3–15)	12.8 ± 1.8 (13)	12.1 ± 2.4 (13)	12.7 ± 1.9 (13)
Trust (3, 3–15)	12.1 ± 1.8 (12)*	11.1 ± 2.1 (11)	11.9 ± 1.9 (12)
Understanding (5, 5–25)	21.4 ± 2.7 (22)*	19.4 ± 3.4 (20)	21.0 ± 2.9 (20)
Researcher characteristics (4, 4–20)	17.2 ± 2.0 (17)*	15.9 ± 2.1 (16)	16.9 ± 2.1 (17)
Environment (4, 4–20)	16.5 ± 2.9 (17)*	14.0 ± 4.2 (14)	16.1 ± 3.3 (16)
Characteristics of consent document (3, 3–15)	12.6 ± 1.8 (12)*	10.6 ± 2.5 (10.5)	12.3 ± 2.1 (12)
Altruism (3, 3–15)	12.9 ± 1.7 (13)	12.7 ± 1.7 (12)	12.8 ± 1.7 (13)

Data are expressed as mean ± SD (median).

* $P < 0.001$ *vs.* nonconsenters.

0.0001), read the consent completely (62.0% *vs.* 43.0%, $P < 0.0001$), and understood completely (77.5% *vs.* 58.4%, $P < 0.0001$) compared with nonconsenters. The mean Flesch-Kincaid grade level of the consent forms was 11.2. Despite this, 85.3% of parents agreed that the consent forms were easy to read. Fifty-two percent of consenters and 55.9% of nonconsenters discussed the study information with others before making a decision (P = not significant). For the most part, these discussions occurred between spouses (40.3% and 47.3%, respectively, P = not significant). Forty-eight percent of consenters and 67% of nonconsenters stated that their child had influenced their decision to participate (P = not significant). Seventy-four percent and 56.5% of consenters and nonconsenters, respectively, believed that the researcher should ask the child's permission to participate in a study ($P = 0.003$). The ages at which consenters and nonconsenters considered it appropriate for the researcher to obtain assent from their child were 11.4 ± 3.9 and 13.2 ± 4.2 yr, respectively ($P = 0.001$). In addition, 97% of consenters reported that the researcher had been friendly and relaxed compared with 87% of nonconsenters ($P < 0.0001$).

Table 4 describes the parents' anxiety and their perceptions of the risks, benefits, and importance of the studies. Overall, consenters had less anxiety and perceived the studies as having lower risk, greater direct and indirect benefits, and greater importance. Furthermore, 31.2% of nonconsenters were more anxious as a result of being asked to have their child participate in a study compared to 8.8% of consenters ($P < 0.0001$). However, because consenters were more likely to have been recruited for a nontherapeutic study, we compared the above variables by study strata to control for the potential confounding effects of the study type. Analysis showed that for both therapeutic and nontherapeutic studies the differences in perceived risk, benefits, and importance between consenters and nonconsenters remained significantly different. However, although consenters for nontherapeutic studies had less self-reported anxiety than nonconsenters, for therapeutic studies, there was no difference in anxiety between groups.

Table 4. Parents' Perceptions* of the Studies Presented

	Consenters	Nonconsenters	All Parents
Risk	1.5 ± 1.9 (1)†	4.3 ± 2.5 (4)	2.0 ± 2.3 (1)
Benefit to child	4.4 ± 3.5 (5)†	2.7 ± 2.2 (3)	4.1 ± 3.4 (4)
Benefit to others	7.8 ± 2.1 (8)†	5.9 ± 2.2 (6)	7.5 ± 2.3 (8)
Importance of study	8.0 ± 1.9 (8)†	5.9 ± 1.9 (6)	7.6 ± 2.1 (8)
Anxiety	6.5 ± 2.8 (7)	7.3 ± 2.5 (8)	6.6 ± 2.7 (7)

Data are expressed as mean ± SD (median).

* Based on visual analog scales, where 10 = high. † $P < 0.001$ *vs.* nonconsenters.

Eighty-nine percent of consenters believed that they had been given "just the right amount" of information regarding the study compared to 59.0% of nonconsenters ($P < 0.0001$). Furthermore, 8.8% and 34.9% of consenters and nonconsenters, respectively, believed that they had been given "too little" information ($P < 0.0001$). Sixty-three percent of consenters thought that the information given was "very clear" compared to 44.2% of nonconsenters ($P < 0.0001$). Both groups thought that the information given verbally was an accurate reflection of the information described in the consent document (100% of consenters *vs.* 97% of nonconsenters). Eight percent of consenters were concerned that participation in a study would affect their child's care compared to 47.2% of nonconsenters ($P < 0.0001$). Furthermore, only 8.6% of consenters thought that participation in a study was "just another thing to worry about," compared with 44.6% of nonconsenters ($P < 0.0001$). Significantly more consenters stated that they would participate in a future study compared to nonconsenters (65.3% *vs.* 44.0%, $P < 0.0001$). The factors that would influence them to make a different decision for a future study are described in table 5.

Exploratory factor analysis of the items in the questionnaire demonstrated that the first eight components displayed eigenvalues of greater than 1. However, results of a scree test suggested that the first five were most meaningful. Items in the questionnaire were said to load on a given component if the loading factor was 0.45 or greater for that component and less than 0.45 for the others.[16] Seven items loaded on the first component labeled the "understanding" component. This compo-

Table 5. Factors that Would Influence Parents to Decide Differently for a Future Study

	Responses	
	No.	%
Consenters		
Increased risks	306	83.4
Study difficult to understand	263	71.7
Felt pressured to consent	240	65.4
Felt uncomfortable with researcher	180	49.0
Use of a placebo	177	48.5
Less time to decide	147	40.1
Nonconsenters		
Fewer risks	50	57.5
More time to decide	42	48.3
Ability to consult with family or M.D.	33	37.9
No placebo	29	33.7
Study was important	28	32.2
Felt no pressure to decide	26	25.3

Percentages are based on the number of subjects who provided information.

nent explained 34.6% of the variance. The remaining components were labeled "uncertainty" (four items, 5.9% variance), "information characteristics" (four items, 5.5% variance), "importance" (four items, 4.9% variance), and "environment" (four items, 3.8% variance).

We also performed bivariate and multivariate analyses of the data. Before multivariate logistic regression analysis, we performed exploratory bivariate analyses of all variables to determine their association with the decision of the parent to consent to their child's participation in one of the research studies. Several of these variables were found to be significantly associated with the decision to consent. These included perceived study risk, perceived benefit to their child and to others, perceived importance of the study, researchers' characteristics, parents' listening to the researcher completely, parents' reading the consent document completely, right amount of information, clarity of information, lower education, older child, low decisional uncertainty, trust, good understanding, good environment, characteristics of consent document, and nontherapeutic study. These factors were subsequently entered into a logistic regression model with backward selection. Multivariate analysis of these factors yielded six factors predictive of consent. Results of these analyses are shown in table 6.

Table 6. Predictors of Consent for Clinical Research

Predictors	Wald Statistic	Significance
Perceived risk of study	−20.0	< 0.0001
Read the consent document completely	13.9	< 0.0001
Characteristics of consent document*	12.9	< 0.0001
Perceived benefits to child	6.0	0.014
Understanding	5.3	0.022
Perceived importance of study	4.3	0.038

* A copy of the questionnaire is available on the ANESTHESIOLOGY Web site at http://www.anesthesiology.org.

Discussion

To our knowledge, this study represents the first to examine factors that influence a parent's decision to allow his or her child to participate in clinical anesthesia and surgery research. Not surprisingly, the perceived risks, benefits, and importance of a study were important determinants of decision making. Although the risks and benefits are intrinsic to any given study, the manner in which they are disclosed is important to ensure that they are not misinterpreted. Indeed, the other factors identified, *e.g.*, the quality and the degree to which the parent read the consent document are important to ensure that the risks and benefits are clearly understood. By identifying these factors, it may now be possible to develop strategies to improve the readability of consent documents and the manner in which study information is presented.

A study of older research subjects identified several factors that influence decisions to consent to participate.[19] These include the subject's age, diagnosis (cancer), and involvement of a caregiver in decision making. Harth *et al.*[20,21] examined the psychologic and sociodemographic data of parents who volunteer their children for clinical research. These authors determined that parents who volunteer their children for research have lower self-esteem, are more introverted, exhibit greater anxiety, and are less educated and more socially disadvantaged compared to parents who decline their child's participation. Our results also showed that consenters were less educated; however, in contrast to Harth's study, we found that consenters tended to have less anxiety than nonconsenters.

Consent for anesthesia and some surgery research is unique in that it is typically sought on the day of surgery. This reflects the nature of anesthesiology practice, wherein the first contact with the patient is typically just before surgery in the preoperative waiting area. The appropriateness of recruitment of subjects at this time has been brought into question given that subjects may be anxious and have limited time in which to make a decision.[22] Mingus *et al.*[23] reported that patients recruited for a hypothetical clinical anesthesia study would prefer to be recruited before the day of surgery in a private setting, in their street clothes, and with the opportunity to consult with their physician. Research associated with risk and consent sought in the preoperative holding room were deemed unacceptable by these subjects. Despite this, all of these subjects felt capable of making a decision regarding participation on the day of surgery. In the current study, the majority believed that there was sufficient time and privacy given for decision making, and only 6.1% strongly agreed that they had felt pressured in making their decision. This is similar to a previous study from our institution that showed that parents of children recruited for anesthesia-related stud-

ies do not feel unduly pressured or coerced when recruited on the day of surgery.[8] Similar results were observed among parturients recruited for obstetric studies.[9] In contrast, one study showed that as many as 25% of subjects feel obliged to participate in research.[24] In the current study, the day on which consent was sought, the amount of time spent explaining the study, and the time allotted to make a decision had no apparent effect on the parents' decisions to consent. Furthermore, the time allotted for decision making for the studies presented here was within the limits described as sufficient (20–30 min) in the study by Mingus *et al.*[23]

Another concern regarding consent sought on the day of surgery is that subjects or their surrogates are likely to feel anxious and, therefore, vulnerable. In our study, parents with higher self-reported anxiety were less likely to consent. In a study by Treschan *et al.*,[25] 8% of subjects recruited for a sham study were more anxious by being asked to participate, and of these, none consented. These results emphasize the importance of disclosing study information in a relaxed, unhurried manner.

That perceived risk was found to be predictive of nonconsent was not surprising given that the primary role of the parent as a surrogate decision maker is to protect the child's welfare.[5] Indeed, several studies have identified risk as a major determinant in decision making.[8,9,19,23] Parents who had poor understanding of the research were also less likely to consent. Several factors have been shown to affect parents' understanding of disclosure for research, including the clarity of the information, how well the parent listened to the researcher, and how thoroughly the parent read the consent document.[7] These findings emphasize the importance of disclosing information in a manner that facilitates understanding. Parents who did not consent to their child's participation seemed to have less trust in the medical system than those who consented. Distrust, particularly as it applies to the risks and benefits of the research, may engender skepticism or misconceptions that hinder the decision-making process. This finding has been reported previously, particularly as it applies to minority populations.[26,27] Given the perfunctory relationship between anesthesiologists and their patients, this issue may be difficult to overcome.

Altruism has been shown to be an important component of decision making. For example, Sugarman *et al.*[28] showed that 76% of subjects participated in research as a way to help others. In developing altruism as a construct, it was our feeling that altruism would be greater among consenters. However, although both groups displayed high levels of altruism, there were no differences between them. This apparent incongruity may reflect a greater conflict between altruism and risk among the nonconsenters such that their desire to help was superseded by their concerns for the risks.

The potential limitations of survey research include nonresponse, self-report, and recall biases. In this study, the number of parents who did not complete the questionnaire was very small such that any bias introduced by nonresponse would have been minimal. In an attempt to reduce the potential for self-report bias, the questionnaires contained no identifying information. In this way, the respondents were more likely to respond honestly, particularly to items that may have been sensitive. Recall bias was also minimized in this study by administering the questionnaire soon after the parents were approached to have their child participate in one of the research studies. An additional consideration was that although we attempted, when possible, to use existing validated measurement tools, there is concern that modification of these tools may have affected their reliability and validity. Given that there are no definitive standards by which to measure criterion validity of some of the constructs, we were unable to formally provide validity information. However, results did show that the items used in this study showed excellent reliability. Finally, when interpreting these results, one must take into account that they were based on relatively low-risk studies. As such, they may not be able to be generalized to studies involving high risk or poor risk–benefit profiles.

Although the recommended guidelines for readability of consent documents suggest an eighth-grade reading level,[2] studies have shown that in practice, this is seldom accomplished.[29–31] Indeed, the consent documents used in this study were written at above the recommended levels. As such, this may have influenced the ability of some parents to understand the consent information. However, we should note that studies reveal that simply reducing the reading level does not guarantee improved comprehension.[32] Furthermore, 85.3% of parents perceived the consent documents as "easy to read," and 87.5% believed that the researcher had "done a good job" in explaining the consent information.

Although it is every investigator's goal to satisfy the sample size requirements of their study in the shortest amount of time, recruitment practices must ensure that all eligible subjects are fully informed and that their individual rights to self-determination or the rights of their surrogate to protect are preserved. This study has identified several factors that influence parents' decisions to consent to their child's participation in clinical research. These results reinforce the need to ensure that investigators' present research information in a relaxed yet professional manner, that the informed consent document is readable and the information is clear, and that the subject or their surrogate fully understand all elements of disclosure. It should also be noted that these results have implications for the recruitment of all research subjects beyond the realms of anesthesia and surgery. Indeed, identification of factors that influence decision making will be important to develop strategies to optimize both the environment and manner in which

consent is sought, to improve subject understanding, and to ensure that the rights and welfare of all research subjects, regardless of discipline, are protected.

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