



Patient Attitudes Toward Granting Consent to Participate in Perioperative Randomized Clinical Trials

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Study Objective: To determine the factors that affect patients' decisions to provide informed consent to participate in perioperative clinical trials.

Design: Survey instrument (questionnaire).

Setting: Urban, tertiary-care, university-affiliated hospital.

Measurements and Main Results: Of 52 patients who had been asked to participate in a randomized control trial (RCT), 43 agreed to be participate in our survey. Almost all consenters (97%), but only 62% of nonconsenters agreed to answer the survey questions ($p = 0.002$). No significant difference in gender, ethnic background, marital status, or education level was found between groups who were or were not willing to participate. Univariate correlates of agreement to participate in RCTs included older age (> 60 yrs; $p = 0.02$), a reassuring attitude conveyed by study personnel ($p = 0.02$), and trust in study personnel ($p = 0.02$). Those who declined participation in clinical trials more frequently indicated that the study made them feel like a "guinea pig" ($p = 0.02$).

Conclusion: Patient age and personal attitudes predict the likelihood of participation in perioperative clinical trials. Neither gender nor race affected willingness to participate. Further work in larger groups is needed to identify predictors of consent and techniques to increase willing participation. © 2004 by Elsevier Inc.

Keywords: Informed consent; medical ethics; patient satisfaction; randomized control trials.

Introduction

The randomized clinical trial (RCT), despite some limitations, remains the "gold standard" for outcome and efficacy research for new treatments and diagnostic tools. The National Institutes of Health and the Food and Drug Administration mandate that those conducting clinical trials recruit participants who are diverse in race, gender, and socioeconomic status.^{1,2} Racial and gender balance are particularly important in trials of new drugs because pharmacokinetics and pharmacodynamics may be affected by gender or race.^{3,4} It has been suggested that members of some demographic groups, such as African Americans, may be less willing to participate in RCTs. Reasons for reluctance or inability to participate may include distrust of the scientific community, presen-

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tation with advanced disease, or comorbidities that preclude enrollment, and language and cultural barriers.^{5,6}

In many studies of patient attitudes toward informed consent for RCTs, the patients surveyed had chronic diseases and, thus, also the luxury of time to make such decisions. Additionally, patients may believe, even if researchers do not encourage such thinking, that trial participation may improve their outcomes.⁷ Because neither consideration may apply in a perioperative environment, the factors that influence consent in this setting should be examined.

We interviewed a subset of patients who consented or declined participation in an ongoing RCT. The goals of our survey were to find demographic or attitudinal differences among consenting and nonconsenting patients and to identify factors that predict successful recruitment of patients in this setting.

Materials and Methods

All studies, including the randomized trials, as well as our use of a questionnaire, were conducted with approval of the University of Chicago Institutional Review Board. We refined a questionnaire through cognitive interviews of 20 patients.⁸ Cognitive interviews provided feedback for revisions to make questions easier to complete for patients with cognitive impairment, poor reading skills, and/or low motivation.* During development of the instrument, a cognitive expert (D.M.) interviewed respondents in-person, one-on-one. The cognitive interviewer asked the respondent to "think aloud" as he answered each question. The interviewer then asked specific probes after some questions (e.g., "What does 'health care provider' mean to you?"). Cognitive interviewing techniques determined that the majority of patients had understood the questions, could recall relevant information, and had used appropriate cognitive strategies to formulate answers.

Between July 1994 and May 1995, one investigator (H.W.) approached 52 patients on the hospital ward 1 to 2 days after surgery to complete a questionnaire. The patients who were asked to complete the surveys had been recruited previously for a variety of perioperative RCTs at the University of Chicago Hospital, including studies of clonidine sympatholysis in vascular surgery ($n = 16$),⁹ methylnaltrexone for treatment of postoperative nausea and vomiting ($n = 17$),¹⁰ and an oral fentanyl lozenge for treatment of postoperative pain ($n = 10$).¹¹ Nonclinical research personnel had approached patients for RCT consent, provided a verbal explanation of the study, and encouraged patients to ask questions and read the consent form; clinician-investigators later spoke with patients who had agreed to confirm their consent. Of the 52 patients identified, 31 had consented and 21 refused to participate in a perioperative RCT.

One investigator (H.W.) was the sole interviewer for this questionnaire. He explained the questionnaire, read

it to patients, and allowed as much time as needed for completion. Responses were selected from multiple choices or yes or no; questions about perceptions of research personnel, anxiety, trust, and understanding allowed for measures of degree: very much, somewhat, not really, or not at all (*Appendix*). The interviewer also asked patients about the reasons for consent or refusal. We sought differences between surgical patients who participated in RCTs conducted by our anesthesia department and those who refused participation. Areas of difference examined included demographics, perception of personnel requesting participation in the trial, perception and understanding of the consent form and process, perception of the health care system in general, and reasons for consent or refusal. We also examined a patient's perception of his physician. A patronizing attitude by the physician or a patient's misinterpretation of the physician's demeanor as condescending may also impact the patient's decision regarding an RCT.¹² A physician's negative attitude towards an RCT could also affect the decision to participate.

The Wilcoxon rank sum test (for continuous variables) and Fisher's exact test (for categorical variables) were used to analyze differences between consenters and nonconsenters. A p -value < 0.05 was considered significant. The study had an 80% power to detect a 50% absolute difference ($p < 0.05$, two-tailed) in consent rates between African Americans and others (67%).

Results

Patients who declined to participate in an RCT were less likely to allow interviews to investigate their motivations. Of the 31 people who agreed to participate in a study, 30 consented to be interviewed about the factors affecting consent; of the 21 people who refused to participate in a study, only 13 agreed to be interviewed ($p = 0.02$). We were unable to determine factors that influenced the nonconsenters who also declined to be interviewed about their reasons for refusal. We did not collect demographic data on those unwilling to discuss their attitudes.

We found no significant difference in gender, ethnic background, marital status, or education level between consenters and decliners (*Table 1*). Older patients (age > 60 yrs) in general were more likely to agree to participate ($p = 0.02$; *Table 2*). There was a nonsignificant trend toward greater participation in RCTs for those patients who asked the advice of others and who read the consent form. Of the 30 people who participated in an RCT, 11 read the consent form; of the 13 nonconsenters, only one person had read the consent form ($p = 0.07$). Reading the consent form did not seem to dissuade a patient from participation. Patients who had read the consent form agreed that it was helpful in understanding the procedure, that it was fairly easy to understand, and that it had some influence on the decision to participate. However, had there been no consent form, all the patients confirmed that, after hearing the explanation of the trial, they would have made the same decision.

*Klock A, Mingay D, Lichtor JL, et al: Refinement of an automated survey to assess inpatient satisfaction with pain control [Abstract]. *Anesth Analg* 1996;82:S237.

Table 1. Demographics of the Respondents

Factors	Consenters (n = 30)	Decliners (n = 13)
Males/females	10/20	3/10
Mean age (yr) +/- SD	54.7 ± 13.52	44.1 ± 7.85
African American	8 (27%)	5 (38%)
Caucasian	14 (47%)	7 (54%)
Hispanic	4 (13%)	0 (0%)
Asian	4 (13%)	1 (8%)
Education*		
Some high school	2 (7%)	0
H.S./GED	7 (23%)	5 (38%)
Some college	9 (30%)	4 (31%)
College	9 (30%)	3 (23%)
Some graduate school	2 (7%)	0 (0%)
Graduate/professional school	1 (3%)	0 (0%)

*One decliner did not divulge educational level.

Table 3 summarizes the respondents' perceptions of the research personnel seeking consent for the RCT. Two statistically significant differences between those who agreed and those who declined to participate were the confidence and trust generated by the research personnel. Those patients who respected and trusted the study personnel were also more likely to consent. More patients who declined than who agreed reported feeling like a "guinea pig" by being part of a study ($p = 0.02$). Consenters and non-consenters alike said that the study personnel answered all their questions fully or very fully. In addition, most consenters were not surprised to be asked to participate in the study, whereas the nonconsenters were somewhat surprised; this difference did not reach statistical significance ($p = 0.09$).

When asked how stressed they felt at certain points in the consent process, there were no significant differences in responses between consenters and decliners. Almost all the patients interviewed said they felt no stress at meeting the study personnel, on reading the consent form, and after reading or hearing about risks and details of the procedure (Table 4). However, when patients heard that

Table 3. Patient Attitudes toward Research Personnel and the Consent Process*

Factor	Consenters (median)	Decliners (median)	p-Value
Assurance of study person	4.6	3.8	0.0173
Feeling like "guinea pig"	1.7	2.7	0.0203
Trusting study person	4.0	3.2	0.0239
Surprised to be asked	2.2	2.6	0.0916
Feeling pressure to consent	1.4	2.0	0.1103
Satisfied by study person	4.2	4.1	0.1875
Respect from study person	4.0	3.8	0.2207
Interest of study person	3.4	3.0	0.3941
Questions answered fully	3.2	3.5	0.6341

*Responses were given on a scale of 1 to 5, with 1 = not at all and 5 = very much.

Table 2. Possible Predictors of Consenting to Perioperative Randomized Controlled Trial

Factor	p-Value
Older age (> 60 yr)	0.019
Reading consent form	0.070
Asked advice of others	0.082
Children	0.195
Education	0.388
Years seeing physician	0.492
Race	0.624
Gender	0.720
Marital status	0.713
Income	0.769

the use of a drug was experimental, 43% of consenters and 46% of nonconsenters reported feeling somewhat stressed. The experimental nature of the drug caused more stress than learning about risk. Both consenters and decliners reported being stressed or not stressed equally during the consent process; stress did not seem to be a predictor of consent.

Factors that were important to patients who consented to participate in an RCT appear in Table 5. Among consenters, the most important factors reported were contribution to medical research and benefiting others and self. Trust in the institution appeared to be of modest importance. Less important factors were advice of others, fear of offending clinicians and receiving poor care, and advice of a person's physician. Altruistic motives and personal benefit were more important influences than a physician's advice.

Those who declined participation were reluctant to justify their actions beyond not wanting to feel like a "guinea pig" (Table 6). Fear of side effects, distrust of hospital, advice of a personal physician, and advice of others were reported as not very important or irrelevant to the decision.

Discussion

Our results suggest that the perceptions and attitudes of patients toward investigators and the institution appeared more important than gender or race in predicting consent to perioperative clinical research trials. Those who were less assured by or trusting of study personnel or who "felt like a guinea pig" were less likely to participate. Among demographic predictors, only age appeared significant; specifically, older patients appeared more willing to participate in RCTs than were their younger counterparts. Although we interviewed a small number of patients, we believe that our detailed interviews of patients who had actually been asked to participate in research in an inpatient setting provide valuable information.

Of those who agreed to participate in the study, 37% read the consent form; of those who declined participation, only 8% had read the consent form. Patients who were receptive to participating in a study may be more willing to take the time to read a consent form, and the

Table 4. Stress During Consent Procedure (consented, n = 30/refused, n = 13)

Stressed Factors	Very Much	Somewhat	Not Really	Not At All	Does Not Apply
Meeting study personnel	0/0	0/2	14/4	14/7	2/0
Reading consent form	0/0	0/0	4/0	6/1	20/12
Reading about risks	0/0	3/3	17/4	8/6	2/0
Reading about procedure	0/0	3/1	22/9	3/3	2/0
Reading about experimental drug	0/1	13/5	13/6	2/1	2/0

consent form did not appear to hinder recruitment. Alternatively, patients may have already decided in advance whether or not to participate before even considering reading a consent form. Our results differ from those of investigators who found that information-seeking patients are less likely to give consent to RCTs.¹³ However, choosing to read a consent form may not always represent information-seeking, but rather may represent courtesy to the investigators or an attempt to delay making a decision. Our finding that few patients actually read the entire consent form may be disconcerting, but it is consistent with our and others' experience in conducting clinical research. (L.A. Fleisher, personal communication). We do not believe that this situation is at odds with Federal Requirements:

"... a written consent document that embodies the elements of informed consent required by §46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed..."¹⁴

Other investigators have reported that although patients should be well informed, consent may be more likely when the consent form is shorter and contains less information. Overly detailed descriptions of potential risks and side effects may frighten patients and lead to refusal to participate.¹³ When Mingus et al.¹⁵ interviewed ambulatory surgery patients to determine their attitudes toward a hypothetical research study, they found several patient preferences: the request should take place at the time of preadmission testing; patients wanted to consult with their physician; the request should be made in a private setting while the patient is dressed in street clothes; and assurance should be given that the investigator would also participate as a subject in the study, if eligible.

Tait *et al.*¹⁶ interviewed parents who had been approached for permission to allow their children to participate in clinical anesthesia studies. Approximately 40% of the children were to undergo cardiac surgery. The consent rate was 68% compared with our rate of 59.6%. They found no demographic differences (child's age, parents' education, race, previous hospital experience, or type of

Table 5. Reasons Given for Consent*

Factor	Very Important	Somewhat Important	Neither Important nor Unimportant	Not very Important	Irrelevant
Contribution to medical research	12	15	1	1	0
Benefit others	15	12	1	1	0
Benefit self	4	13	11	1	0
Dissatisfaction with current treatment	0	3	5	9	12
Like people conducting trial	3	6	8	8	4
Trust in hospital	2	8	12	4	3
Advice of personal doctor	0	0	0	1	28
Afraid of offending and getting poor care	0	0	1	1	27
Advice of others	1	1	1	0	26

*Patient sample = 29.

Table 6. Reasons Given for Declining to Participate*

Factor	Very Important	Somewhat Important	Neither Important nor Unimportant	Not very Important	Irrelevant
Fear of side effects	0	0	4	5	4
Feel like guinea pig	0	3	2	7	1
Distrust of hospital	0	1	1	5	6
Advice of personal doctor	0	1	0	6	6
Advice of others	0	0	0	0	13

Patient sample = 13.

surgery) between consenters and nonconsenters. Our results were similar, except that our older patients (age > 60 yrs) were more likely to consent. Tait *et al.* also found that parents who felt more anxious because researchers sought consent were more likely to decline. Similarly, we found that a patient's perception of the research staff ("assurance," "trusting") were predictors of consent (*Table 3*). Thus, we suspect that parents use similar factors in their decision-making for their children that patients use when making decisions for themselves.

Dorantes *et al.*¹⁷ gave written questionnaires to parturients who had been approached for labor epidural trials. They detected no demographic differences between consenters and refusers. Most consenters seemed motivated by altruism; fear of pain was the most common motivation for refusers. Only one patient felt coerced to participate. They found, as we did, that patients who read the consent form completely were more likely to consent. Patients who were less anxious or who had previously participated in research projects were more likely to have given consent.

Verheggen *et al.*⁷ interviewed adult patients who had been approached for a variety of unspecified clinical trials in a wide variety of departments in a Dutch university hospital. Of patients asked to participate in trials, 87% consented, and 88% of these patients agreed to be interviewed. As in our study, the investigators found that a higher percentage (35%) of those who refused trial participation refused to be interviewed about their reasons as well. They detected differences in patient motivations depending on whether the relevant health problem was preexisting or newly diagnosed. Time requirements were a concern of both groups. Patients with new diagnoses appeared to expect better medical treatment within the trial. Patients with established diseases were hopeful of receiving improved comfort and more influenced by possible risks of the trials and the acuity of their illnesses. However, their results from a possibly more homogenous community with a greater sense of societal obligation may be less generalizable to other, more diverse settings.

Myles *et al.*¹⁸ surveyed a large group of patients about a hypothetical perioperative clinical trial. Multivariate predictors of recruitment were patient age >45 years [odds

ratio (OR), 1.44; 95% confidence interval (CI), 1.08 to 1.93], English-speaking at home (OR, 1.49; 95% CI, 1.0 to 2.21), and male researcher-male patient interaction (OR, 1.37; 95% CI, 1.20 to 1.57). Whether patients would be randomized before or after consent did not appear to change consent rate, which averaged from 53% to 60%.

Further research is needed to determine the relationship between personality characteristics of patients, their desire for information, and their willingness to give consent. Our respondents indicated, however, that a patient's perception of the person requesting participation is important (*Table 3*). Patients who consented to participate had a favorable impression of the study person asking their permission. Because our study sample was small and research personnel were not randomly allocated to seek consent, we are hesitant to make sweeping comments about the nature of the subject-researcher relationship. Possible biases (e.g., older patients preferring an older investigator) could not be detected. The relative effects of patient and research personnel characteristics in predicting good "bonding" and likelihood of consent remain to be verified. In our study, some patients who did not consent and admitted to feeling like a "guinea pig" also expressed less satisfaction with study personnel.

Our work suggests that racial, gender, and economic characteristics may be less important than the interactions between patients and researchers in determining whether patients consent to clinical trials. Clinician-researchers might endeavor to engender patients' respect and assurance. We agree that consent should be obtained in a nonpressured and noncoercive environment. Although some institutions require that consent for perioperative studies be obtained before the day of surgery, we do not believe that such measures are necessary.

Our work has some limitations. We studied a small number of patients. Decliners were less likely to complete the survey. Because those who refused to complete the survey may have had negative attitudes about research, however, we believe our results remain valid. The fact that many of our nonconsenters to RCTs could not say which of the factors about which we queried them were important in their decisions (*Table 6*), however, suggests that

further work is needed to uncover the motivations of nonconsenters. We questioned patients on postoperative day 1 or 2, after they had consented or declined to be studied. Residual anesthetic effects and pain may have had an effect on their judgments. Ideally, patients should have been interviewed shortly after they agreed or declined to participate.

There are several strengths of our approach. We surveyed patients who had been asked to participate in real, not hypothetical trials. We used cognitive interviewing to develop and refine the survey instrument. Lastly, we administered the surveys face-to-face by a single interviewer, as opposed to collecting paper questionnaires.

Given the increasingly fragmented nature of preoperative evaluation and the increase in outpatient surgery, we believe it will become more difficult to recruit patients for an RCT in the perioperative setting. Yet, an RCT remains the gold standard for determining the efficacy of new treatments. If our goal is to increase RCT enrollment, then further work is needed to identify methods to increase patient consent. However, efforts to increase enrollment may have unintended consequences in limiting patient autonomy. We believe both goals are worthy and must be considered by clinical researchers.

APPENDIX

PATIENT SURVEY OF ATTITUDES TOWARDS CLINICAL RESEARCH PROJECTS AT THE UNIVERSITY OF CHICAGO

Name _____ Room Number _____
 Title of Study _____ IRB # _____
 Principal Investigator _____ Patient ID # _____
 Date _____ Consent Interview date _____
 Time _____ Consent Interview time _____
 Date of Surgery _____ Length of consent interview _____
 inpatient/outpatient (circle one) Male/female

Person who approached patient for consent _____
 Title of person who approached patient for consent _____
 CONSENTED/REFUSED (circle one)

0. Do you recall being asked to participate in a research project? _____ yes/no

***If no, answer only #1–16**

1. What is your age? _____
2. How would you describe your race? _____
 - a) Black/African-American
 - b) White
 - c) Hispanic
 - d) Asian
 - e) other
3. What is the highest level of education that you have completed?
 - a) some high school, did not graduate
 - b) high school graduate/GED
 - c) some college, did not graduate
 - d) graduated from college with BA
 - e) some graduate/professional school

- f) graduate/professional degree
4. What is your marital status?
 - a) married
 - b) single, never married
 - c) divorced
 - d) widowed
5. How many children do you have? _____ (living children, if they ask)
6. What is your occupation? _____. If retired, what occupation did you have for the longest period of time _____
- 6a. What is your annual household income?
 - a) < \$ 10,000
 - b) 10,000–20,000
 - c) 20,000–40,000
 - d) 40,000–60,000
 - e) 60,000–80,000
 - f) > 80,000
7. How would you compare your experiences in the hospital with previous hospital stays?
 - 5 much better
 - 4 better
 - 3 the same
 - 2 worse
 - 1 much worse
 - 0 never been in the hospital
8. Have you ever participated in any kind of medical research study or project in a hospital? _____ yes/no/don't know
 - a. **if so, would you say that it was a positive or negative experience?**
 - 5 very positive
 - 4 somewhat positive
 - 3 neither positive nor negative
 - 2 somewhat negative
 - 1 very negative
9. Do you know anyone who has? yes/no
 - a. **if so, in general, was it a positive or negative experience for them?**
 - 5 very positive
 - 4 somewhat positive
 - 3 neither positive nor negative
 - 2 somewhat negative
 - 1 very negative
10. In a typical year, how many times do you visit your regular doctor?
 - a) 0
 - b) 1–2
 - c) 2–5
 - d) 6–10
 - e) >10
 - f) have no regular doctor
11. How long have you been seeing your personal doctor?
 - a) 0–1 year
 - b) 1–3 years
 - c) 3–7 years
 - d) 7–10 years
 - e) > 10 years
 - f) have no regular doctor
12. Would you recommend him or her to a friend or relative? _____ yes/no/not applicable

-
13. If a friend of yours were having the same operation that you did/were having a baby, would you recommend your surgeon/obstetrician? yes/no
14. And the anesthesiologist? yes/no/do not remember
15. Did you consult with anyone before deciding whether to participate in this study?
yes/no/do not remember
- a. **if yes, whom did you ask for advice? (circle all that apply)**
- doctor
 - spouse
 - parent
 - child
 - friend
 - nurse
 - other: _____
- Did you read the consent form? Yes/No/Don't Remember; if no skip to #20**
16. How helpful was the consent form in helping you understand the procedure?
- 5 very helpful
 - 4 somewhat helpful
 - 3 not very helpful
 - 2 not at all helpful
 - 1 do not remember
 - (0 no opinion)
17. Did the consent form contain too much or too little information or the right amount?
- too much
 - too little
 - just right
 - do not remember
18. How difficult or easy do you think most people would find the words in the consent form to understand?
- 4 very easy
 - 3 fairly easy
 - 2 somewhat difficult
 - 1 very difficult
 - 0 do not remember
19. How much influence did the consent form have on your decision whether or not to participate?
- 5 a very strong influence
 - 4 a significant influence
 - 3 some influence
 - 2 a little
 - 1 none at all
 - 0 do not remember
- b. If there had been no consent form would your decision have been the same based on the doctor's speech? yes/no/don't know
20. About how old was the doctor who approached you about the study?
- <30
 - 30-40
 - 40-50
 - 50-60
 - 60-70
 - do not remember
21. How would you describe his/her race? _____
- Black/African-American
 - White
 - Hispanic
 - Asian
 - Other _____
 - do not remember
22. Did the study person treat you with respect?
- 4 very much so
 - 3 somewhat
 - 2 not really
 - 1 not at all, total lack of respect
 - 0 do not remember
23. In general how reassuring or upsetting did you find the study person's attitude?
- 5 very reassuring
 - 4 fairly reassuring
 - 3 neither reassuring nor upsetting
 - 2 somewhat upsetting
 - 1 very upsetting
 - 0 do not remember
24. How satisfied were you with the knowledge and skill of the study person?
- 5 very satisfied
 - 4 fairly satisfied
 - 3 neither satisfied nor disappointed
 - 2 somewhat disappointed
 - 1 very disappointed
 - 0 do not remember
25. Did s/he answer all your questions fully?
- 4 very fully
 - 3 fully
 - 2 not very fully
 - 1 not at all
 - 0 do not remember
26. Do you feel that the consent interview took too long? yes/no/do not remember
27. Did his/her main interest seem to be in the research, in you as a patient, or a combination?
- 5 complete interest in you and your needs
 - 4 interested in you mostly, but the research was also important
 - 3 equal interest in patient and research
 - 2 interested mostly in the research, but also cared about you
 - 1 complete interest in the research
 - 0 do not remember
28. Did you feel that you could trust the person who approached you about the study?
- 4 very much so
 - 3 somewhat
 - 2 not really
 - 1 not at all
 - 0 do not remember
29. Did you feel pressured to consent?
- 4 very much so
 - 3 somewhat
 - 2 not really
 - 1 not at all
 - 0 do not remember
30. Did you feel that the interviewer rushed you to make a decision?
- 4 very much so
 - 3 somewhat
 - 2 not really
 - 1 not at all
 - 0 do not remember
-

31. Did you feel like a "guinea pig"?
- 4 very much so
 - 3 somewhat
 - 2 not really
 - 1 not at all
 - 0 do not remember
32. Did your personal doctor speak to you about the study before you were approached? yes/no/don't remember
33. Did your surgeon speak to you about the study before you were approached? yes/no/don't remember
34. How well do you feel that you understood the procedure?
- 5 very well
 - 4 fairly well
 - 3 well
 - 2 not very well
 - 1 not at all
 - 0 do not remember
- a. Did the doctor use words that are too difficult for most people to understand? yes/no/do not remember
35. How stressed did you feel at these points in the consent process:
- 4 very stressed
 - 3 somewhat
 - 2 not really
 - 1 not at all
 - 0 does not apply
- a. meeting the study person 1 2 3 4
- b. reading the consent form (0) 1 2 3 4
- c. reading/hearing about the risks (0) 1 2 3 4
- d. reading/hearing the details of the procedure (0) 1 2 3 4
- e. reading/hearing that use of the drug is experimental (0) 1 2 3 4
36. Before you entered the hospital, if asked "would you be willing to participate in any study", would your answer have been the same as when asked to participate in this study? yes/no/don't know
- a. if not, what changed your mind?** _____
- something in the consent form? yes/no
- specify:
- something the research person said or did? yes/no
- specify:
37. How much did it surprise you to be asked to participate in the study?
- 4 very much
 - 3 somewhat
 - 2 not really
 - 1 not at all
 - 0 do not remember
38. How important were these reasons in your decision to consent:
- 5 very important
 - 4 somewhat important
 - 3 neither important nor unimportant
 - 2 not very important

- 1 irrelevant
 - a. to contribute to medical research 1 2 3 4 5
 - b. to benefit others 1 2 3 4 5
 - c. to benefit self 1 2 3 4 5
 - d. dissatisfaction with current treatment 1 2 3 4 5
 - e. liked people conducting the trial 1 2 3 4 5
 - f. trust in the hospital 1 2 3 4 5
 - g. advice of personal doctor 1 2 3 4 5
 - h. advice of others 1 2 3 4 5
 - i. afraid to alienate/offend the doctor(s) resulting in poor care 1 2 3 4 5
 - j. other _____
- Or:
- How important were these reasons in your decision to refuse:
- 5 very important
 - 4 somewhat important
 - 3 neither important nor unimportant
 - 2 not very important
 - 1 had nothing to do with it
- a. fear of side effects 1 2 3 4 5
- b. fear of being a guinea pig 1 2 3 4 5
- c. distrust of hospital 1 2 3 4 5
- d. advice of personal doctor 1 2 3 4 5
- e. advice of others 1 2 3 4 5
- f. other _____
- Did being in the study improve your opinion of the medical community? yes/no/stayed the same
- of your anesthesiologist? yes/no/stayed the same
- of your surgeon? yes/no/stayed the same

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