A Preadmission Telephone Call to Initiate the Consent Process for Clinical Anesthesia Research

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Abstract Consent for a clinical anesthesia research trial is frequently sought in hospital on the day of surgery. This time is often associated with increased anxiety, diminished privacy, and limited opportunity for reflection. Our objective was to determine whether a preadmission telephone call on the day before surgery resulted in greater satisfaction compared to the traditional practice of initiating the consent process on the day of surgery. We randomized 124 patients eligible for participation in a minimal-risk clinical anesthesia trial to receive either a preadmission telephone call on the day before surgery to initiate consent (Telephone group; $n = 62$), or no telephone call (Control group; $n = 62$). In the Telephone group, 21 patients (33.9%) were successfully contacted by telephone, whereas 41 patients (66.1%) were not contacted. Both the Telephone and Control groups reported similar understanding regarding the purpose of the trial. Both groups similarly agreed that the time and setting of recruitment and consent were appropriate. Patients in both groups reported having enough time to consider their participation in the trial. Few patients in either group reported feeling anxious at the time of consent or pressured to participate in the trial. Finally, patients in both groups were equally satisfied with the consent process. *Implications:* A preadmission telephone call on the day before surgery to initiate the consent process for a minimal-risk clinical anesthesia research trial does not improve satisfaction among consenting patients

compared to initiating consent in hospital on the day of surgery, and can be an impractical method to initiate the consent process.

Key words consent · clinical · timing

Introduction

The ideal time to obtain consent for a clinical anesthesia research trial is controversial. Because of the ongoing shift away from preoperative hospital admission in North America, the first encounter between the surgical patient and the anesthesiologist most often occurs on the day of surgery. For this reason, consent for anesthesia, as well as consent for clinical anesthesia research trials, is sought on the same day as surgery [1]. Obtaining consent for a clinical trial on the day of surgery affords the patient an opportunity to discuss the research protocol in person with the investigator(s). Retrospective studies have indicated that patients are comfortable with the practice of consent for clinical anesthesia research trials on the day of surgery [1–3]. Nonetheless, medical ethicists and institutional review boards (IRB) are increasingly resistive to this process as the hospital can be regarded as a coercive environment. Moreover, the immediate preoperative setting may prohibit adequate time for reflection, thus precluding “informed” consent [1, 4]. High consent rates may possibly signify excess pressure from the investigator(s), whereas a low rate of consent may indicate residual doubt or lack of trust on the part of the patient [5, 6].

In view of the potential shortcomings of the same-day consent process for clinical anesthesia research trials, a preadmission telephone call to initiate the consent process has been introduced in 19% of North American centers [7]. However, a preadmission telephone call may provoke undue anxiety [8] and may even undermine patient confidentiality [1]. Our objective was to determine whether a preadmission telephone call to initiate the consent process on the day before surgery resulted in greater satisfaction among consenting patients compared to the

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traditional practice of initiating consent in hospital on the same day as surgery. We hypothesized that satisfaction of patients who consented to participate in a minimal-risk clinical anesthesia research trial would not be affected by a preadmission telephone call to initiate the consent process.

Methods

This study (henceforth named the “Telephone” study) received IRB approval and was linked onto an ongoing minimal-risk clinical anesthesia trial at our institution entitled “A randomized, controlled trial evaluating the efficacy and complications of interscalene block using the nerve stimulator vs paresthesia technique” (IRB approval date 02/26/04, Principal Investigator: Dr. Gregory A. Liguori; henceforth named the “Paresthesia vs Nerve Stimulator” study). The Paresthesia vs Nerve Stimulator study was a prospective randomized trial comparing the paresthesia- and peripheral nerve stimulator-guided techniques for interscalene brachial plexus block. Patients eligible for inclusion in the Paresthesia vs Nerve Stimulator study were those aged between 18 and 70 years undergoing arthroscopic shoulder surgery under interscalene block, the latter scheduled to be administered by one of that study’s five investigators. Exclusion criteria were any contraindication to interscalene block, patient refusal, pregnancy, dementia, severe pulmonary disease, or preexisting neurologic dysfunction. Consent for the Paresthesia vs Nerve Stimulator study was routinely obtained by one of that study’s investigators in the operating room holding area on the day of surgery. The two-page consent form for the Paresthesia vs Nerve Stimulator study stated that participation involved “no additional risks over and above those inherent to the anesthetic”.

For the purpose of recruitment for the Telephone study, we identified all patients eligible for the Paresthesia vs Nerve Stimulator study appearing on the operating room schedule as published at approximately 3:00 P.M. on the day before surgery. All patients eligible for the Paresthesia vs Nerve Stimulator study were randomly assigned by computer-generated randomization tables to receive either (1) a preadmission scripted (Appendix I) telephone call at home on the day before surgery to familiarize patients with the nature of the Paresthesia vs Nerve Stimulator study, thereby initiating the informed consent process, or (2) no telephone call. Randomization assignment cards remained in sealed opaque envelopes that were opened sequentially as each patient was deemed eligible for inclusion in the Telephone study. All telephone calls were placed by the same research assistant (J.L.) on the day before surgery. (For surgeries performed on Monday, telephone calls were placed on the preceding Friday.) A maximum of two attempts were made to contact patients by telephone at least 30 min apart between 3:00 and 6:00 P.M. on the day before surgery at the primary telephone number listed in the medical chart. No voice messages were left because of concerns for patient confidentiality. Therefore, patients

were initially approached, in a random fashion, about the Paresthesia vs Nerve Stimulator study either by telephone on the day before surgery (Telephone group) or in the holding area on the day of surgery (Control group), the latter being the usual consent practice at our institution.

Recognizing that (1) patients would still partake in a consent discussion for the Paresthesia vs Nerve Stimulator study in the holding area on the day of surgery, (2) a preadmission telephone call carried essentially no risk for the patient, and (3) obtaining consent for a study designed to investigate the consent process would have been problematic, informed consent was waived by our IRB for participation in the Telephone study. The investigators who obtained consent for the Paresthesia vs Nerve Stimulator study were blinded as to which patients received a preadmission telephone call and which patients did not.

Prior to discharge from hospital, all consenting patients were given an information letter (Appendix II) and questionnaire (Table 1) to take home, complete, and return to us by mail in a self-addressed, prestamped envelope. The questionnaire was developed to identify patients’ concerns, attitudes, and perceptions of the consent process for clinical anesthesia research trials [2]. The questionnaire was designed for patients who had consented to participate in a clinical trial. It investigated six areas of potential concern regarding the consent process, “Comprehension”, “Situation” (privacy, time), “Obligation” (pressure), “Motivation”, “Compunction” (regrets), and “Satisfaction”. Responses were organized into a 5-point Likert scale of agreement (1 = strongly disagree, 2 = disagree, 3 = undecided, 4 = agree, 5 = strongly agree), with the exception of Satisfaction, which was scored according to a 100-mm Visual Analog Scale (VAS; 0 mm = least satisfied, 100 mm = most satisfied). Patients who refused to participate in the Paresthesia vs Nerve Stimulator study were excluded from the primary Telephone study analyses, but were given a modified questionnaire (Table 2) in order to capture reasons for refusal. If we did not receive the completed questionnaire within 2 weeks of discharge, those patients were contacted by telephone as a reminder to complete and submit their questionnaire.

In a recent retrospective study using the same instrument [2], 76 patients rated their satisfaction (100-mm VAS) with the traditional practice of initiating the consent process on the same day as surgery. The mean VAS satisfaction score in that study was 71 mm with a standard deviation of 30 mm [2]. An improvement in the mean VAS satisfaction score to 90 mm could represent a significant improvement in the consent process for clinical anesthesia research trials. We calculated that 32 patients per group would be required to detect a 20% difference in VAS satisfaction scores with 80% power and a significance level of 5%. Intention-to-treat data analysis was undertaken using Statview[®] version 5.0 (SAS Institute Inc., Cary, NC, USA). Categorical data were analyzed using the chi-square test. Continuous parametric data were analyzed using the unpaired Student’s *t*-test and are reported as mean $\pm$ standard deviation. Nonparametric data were analyzed using the Mann–Whitney *U*-test with the Bonferroni correction for multiple comparisons and are

Table 1. Questionnaire and responses for patients who consented to participate in the Paresthesia vs. Nerve Stimulator study

	Telephone group (<i>n</i> = 25)	Control group (<i>n</i> = 32)	<i>p</i> Value
I am aware that I participated in an anesthesia research study	5 (4, 5)	5 (5, 5)	n.s.
I was asked to participate in the study at the appropriate time and place	4 (4, 5)	5 (4, 5)	n.s.
I was asked to participate in the study at the ideal time and place	4 (3, 5)	4 (3, 5)	n.s.
I felt anxious when I was asked to participate in the study	2 (1, 4)	2 (1, 4)	n.s.
I understood the purpose of the study before I agreed to participate	5 (4, 5)	5 (4, 5)	n.s.
I understood the benefits and risks of the study before I agreed to participate	4 (3.75, 5)	4 (4, 5)	n.s.
The study was well explained to me before I agreed to participate	5 (4, 5)	4 (4, 5)	n.s.
I had enough time to consider the study before I agreed to participate	4 (2, 5)	4 (2, 5)	n.s.
I had enough privacy to consider the study before I agreed to participate	4 (4, 5)	4 (2, 5)	n.s.
I read and understood the consent form before I agreed to participate	4 (3.75, 5)	4 (4, 5)	n.s.
I discussed the study with someone else before I agreed to participate	1 (1, 2)	1 (1, 1)	n.s.
I wished to discuss the study with someone else before I agreed to participate	2 (1, 4)	1 (1, 2)	n.s.
Participation in the study was voluntary	5 (5, 5)	5 (5, 5)	n.s.
I could have withdrawn from the study at any time without affecting my medical care	5 (4.25, 5)	5 (4, 5)	n.s.
I felt anxious about participating in the study	2 (1, 4)	1 (1, 2)	n.s.
I felt pressured to participate in the study	1 (1, 2)	1 (1, 1)	n.s.
I felt obligated to participate in the study	1 (1, 2.25)	1 (1, 4)	n.s.
Participation in the study is important	4 (3, 5)	5 (3.25, 5)	n.s.
Participation in the study will benefit other patients in the future	4 (3, 5)	4 (4, 5)	n.s.
Participation in the study will contribute to medical knowledge	4 (3.75, 5)	4 (4, 5)	n.s.
My medical care would be jeopardized if I did not participate in the study	1 (1, 1)	1 (1, 1)	n.s.
I regret participating in the study	1 (1, 2)	1 (1, 1.5)	n.s.
The study put my health and/or well-being at risk	1 (1, 2)	1 (1, 1)	n.s.
I suffered from one or more complications as a result of my participation in the study	1 (1, 2)	1 (1, 1)	n.s.
I would participate in another study similar to this one	4 (3, 5)	4 (3.5, 5)	n.s.
Measure of satisfaction with the consent process (0–100 mm VAS; mean $\pm$ SD)	76.7 $\pm$ 27.4	78.8 $\pm$ 20.9	n.s.

Responses are presented as median (25th, 75th percentiles) scores corresponding to 5-point Likert scale of agreement:

1 = strongly disagree; 2 = disagree; 3 = undecided; 4 = agree; 5 = strongly agree.

VAS = Visual Analog Scale; SD = standard deviation; *n* = number of patients; n.s. = nonsignificant.

Table 2. Questionnaire and responses for patients who refused to participate in the Paresthesia vs. Nerve Stimulator study

	Telephone group (<i>n</i> = 4)				Control group (<i>n</i> = 2)	
	Pt #1	Pt #2	Pt #3	Pt #4	Pt #1	Pt #2
I was asked to participate in an anesthesia research study	5	5	3	5	1	1
I was asked to participate in the study at the appropriate time and place	5	2	5	1	–	–
I was asked to participate in the study at the ideal time and place	5	1	5	1	–	–
I felt anxious when I was asked to participate in the study	3	2	4	–	–	–
I understood the purpose of the study before I declined to participate	5	5	5	1	–	–
I understood the benefits and risks of the study before I declined to participate	5	5	5	1	–	–
The study was well explained to me before I declined to participate	5	5	5	1	–	–
I had enough time to consider the study before I declined to participate	5	5	5	1	–	–
I had enough privacy to consider the study before I declined to participate	5	5	5	3	–	–
I read and understood the consent form before I declined to participate	5	1	5	1	–	–
I discussed the study with someone else before I declined to participate	1	1	1	1	–	–
I wished to discuss the study with someone else before I declined to participate	1	1	1	2	–	–
Participation in the study was voluntary	5	5	5	5	–	–
I could have withdrawn from the study at any time without affecting my medical care	5	5	5	–	–	–
I felt anxious about participating in the study	3	1	2	–	–	–
I felt pressured to participate in the study	1	1	1	1	–	–
I felt obligated to participate in the study	1	1	1	1	–	–
Participation in the study is important	3	5	1	3	–	–
Participation in the study will benefit other patients in the future	4	4	3	3	–	–
Participation in the study will contribute to medical knowledge	4	4	3	3	–	–
Measure of satisfaction with the consent process (0–100 mm VAS; mean $\pm$ SD)	86	77	49			

Responses are presented as individual scores corresponding to 5-point Likert scale of agreement:

1 = strongly disagree; 2 = disagree; 3 = undecided; 4 = agree; 5 = strongly agree.

Pt = patient; VAS = Visual Analog Scale; SD = standard deviation; *n* = number of patients; – = question incomplete.

Table 3. Patient characteristics

	Telephone group (<i>n</i> = 62)	Control group (<i>n</i> = 62)	<i>p</i> Value
Gender (M/F)	43/19	39/23	n.s.
Age (years)	46.2 ± 13.1	45.2 ± 15.2	n.s.
Type of shoulder surgery (<i>n</i>)			
Arthroscopic capsular release	4	5	n.s.
Arthroscopic labral repair	10	12	n.s.
Arthroscopic rotator cuff repair	19	17	n.s.
Arthroscopic decompression	11	15	n.s.
Arthroscopic stabilization	7	8	n.s.
Other	11	5	n.s.

n = Number of patients; n.s. = nonsignificant.

presented as median score with the 25th and 75th percentiles in parentheses.

Results

We randomized 124 consecutive patients to receive either a preadmission telephone call or no telephone call. Patient demographics are presented in Table 3. Of the 62 patients selected to receive a telephone call, 21 (33.9%) patients were successfully contacted, whereas 41 (66.1%) patients were not successfully contacted. Figure 1 displays the number of patients in each group who were approached to participate in the Paresthesia vs Nerve Stimulator study, the number of patients who consented to participate in the Paresthesia vs Nerve Stimulator study, and the number of questionnaires returned. Table 4 lists the reasons for which patients were not approached to participate in the Paresthesia vs Nerve Stimulator study. Importantly, the proportion of patients who consented to participate in the Paresthesia vs Nerve Stimulator study was similar between groups [Telephone

Table 4. Reasons for which patients were not approached to participate in the Paresthesia vs. Nerve Stimulator study

	Telephone group (<i>n</i> = 31)	Control group (<i>n</i> = 20)
Investigator's choice	3	2
Change in attending anesthesiologist to noninvestigator	3	1
Change in surgical procedure	5	4
Language barrier	1	2
Insufficient time for recruitment and consent	4	0
Surgical request for long-acting local anesthetic ^a	6	5
Requirement for use of peripheral nerve stimulator	2	1
Research assistant unavailable	4	3
Reason not specified	3	2

^a Paresthesia vs. Nerve Stimulator study protocol permitted intermediate-acting local anesthetic only for interscalene block.

n = number of patients.

group: 27 consented out of 31 approached (87.1%) vs Control group: 37 consented out of 42 approached (88.1%); *p* > 0.999].

Questionnaires were distributed to all 73 patients who were approached to participate in the Paresthesia vs Nerve Stimulator study. Sixty-three patients completed and returned their questionnaires (response rate: 86.3%). Specifically, 36 (57.1%) patients returned their questionnaires within 2 weeks of discharge, whereas 27 (42.9%) patients returned their questionnaires after a reminder telephone call.

For patients who consented to participate in the Paresthesia vs Nerve Stimulator study, questionnaire results are presented in Table 1. Consenting patients in both groups reported a similar degree of understanding regarding the purpose of the clinical anesthesia trial for which they consented to participate, the written consent form, and the risks and benefits of the trial before agreeing to participate. Both groups similarly agreed that the time and setting of recruitment and consent for the trial was

Fig. 1. Flow diagram of subject progress through the phases of the Telephone study. *n* = Number of patients. *Patients analyzed in the same group per intention-to-treat approach.

Table 5. Reasons for which patients refused to participate in the Paresthesia vs. Nerve Stimulator study

	Telephone group (<i>n</i> = 4)	Control group (<i>n</i> = 5)
Anxiety	0	2
Concern that participation would delay surgery or prolong hospitalization	1	0
Patient wanted same anesthetic as performed for previous shoulder surgery	1	0
Patient wanted to be “asleep”	0	1
No reason given	2	2

n = Number of patients.

appropriate. Patients in both groups reported having enough time and privacy to consider their participation in the trial. Few patients in either group reported feeling anxious at the time of consent or obligated or pressured to participate in the trial. Most patients in both groups were aware that participation in the trial was voluntary, and that they could withdraw from the trial at anytime without consequence. Few patients in either group reported regret about participating in the trial. Finally, patients in both groups were equally satisfied with the consent process.

Four patients in the Telephone group refused to participate in the Paresthesia vs Nerve Stimulator study, whereas five patients in the Control group refused to participate in the Paresthesia vs Nerve Stimulator study (Fig. 1). The stated reasons for refusal are presented in Table 5.

Discussion

The ideal time to initiate the consent process for clinical anesthesia research trials is controversial. This study was borne of a growing demand from our IRB to initiate the consent process for clinical anesthesia trials prior to the day of surgery. Our results suggest that a preadmission telephone call on the day before surgery to initiate the consent process for a minimal-risk clinical anesthesia trial does not improve satisfaction among consenting patients regarding the consent process compared to the traditional practice of initiating consent in hospital on the same day as surgery. The satisfaction scores obtained from both groups in this study are similar to those previously reported for patients who had been approached to participate in a clinical anesthesia trial on the same day as surgery [2]. Moreover, a preadmission telephone call does not appear to reduce the anxiety, pressure, or obligation potentially associated with the consent process for participation in a clinical anesthesia trial.

Importantly, our results also highlight the practical limitations of a preadmission telephone call on the day before surgery. We were unable to contact 41 of the 62 (66.1%) patients randomized to receive a telephone call on the day before surgery. One explanation for our low contact rate may be that many people were still at the workplace

when the telephone calls were placed, that is, between 3:00 and 6:00 P.M. on the day before surgery. Telephone calls placed during “dinnertime” (i.e., between 6:00 and 8:00 P.M.) may have improved our contact rate, but calls placed during this time period can disturb patients and their families, and ultimately diminish patient satisfaction. The operating room schedule at our institution is published at 3:00 P.M., therefore telephone calls cannot be placed any earlier. Furthermore, our contact rate may have been improved if we had allowed for contact with spouses or other family members as a surrogate for patient contact, or if we had allowed for voice messages to be left on the patients’ answering machines or voicemail instead of direct contact with the patient. We purposefully avoided these “indirect” methods of contact to protect patient confidentiality. In view of our low contact rate, we believe that the introduction of a mandatory preadmission telephone discussion to initiate the consent process on the day before surgery would grossly restrict patient recruitment and undermine clinical anesthesia research at our institution.

We analyzed our data using an intention-to-treat approach, such that all patients randomized to receive a telephone call were analyzed in the same group regardless of being successfully contacted. We selected an intention-to-treat analysis because socioeconomic and geographic factors, as well as patient personality features, may have contributed to our low contact rate and should be reflected in our results. For example, our ambulatory sports surgery program attracts active young patients who have sustained a minor sports-related shoulder injury. As such, these patients may not be at home to answer the telephone on the day before surgery. Additionally, some patients may choose not to talk on the telephone on the day before surgery, or choose not to answer calls from unfamiliar telephone numbers as displayed on “caller ID.” One possibility to improve the rate of contact prior to the day of surgery would be for an anesthesia research assistant to initiate the consent process in person at the time of each patient’s preoperative surgical consultation. Any such meeting, however, would require coordination between the patient, the surgeon’s office, and the anesthesia research department, which is often impractical.

We cannot exclude a Type II error from our present findings. Post-hoc power analysis using the satisfaction scores obtained from both groups in this study reveals that we would require 4,154 patients (2,077 per group) to detect a significant 2.1% difference in VAS satisfaction scores between the Telephone and Control groups, with 5% significance and 80% power.

Because so few patients in either group refused to participate in the Paresthesia vs Nerve Stimulator study, we could not perform any meaningful group statistical analyses on data accumulated from their completed questionnaires. We present the individual responses (Table 2) for completeness. It is noteworthy, however, that two of the five patients in the Control group who refused to participate in the Paresthesia vs Nerve Stimulator study reported anxiety as the reason for their refusal compared to none in the Telephone group (Table 5).

Table 6. Guidelines for the timing of consent for clinical anesthesia research trials at the Hospital for Special Surgery

Grade	Description	Time to consider participation	Examples
1	A straightforward project of low complexity with minimal (if any) risks over and above those associated with the procedure	Consent may be obtained on the day of surgery and anesthesia	Prospective observational data collection A randomized trial comparing two or more processes currently practiced at HSS
2	A project of moderate complexity which may involve risks over and above those associated with the procedure	Consent must be obtained prior to the day of surgery and anesthesia	A project utilizing a process not currently practiced at HSS A project requiring a significant time commitment on the part of the participant
3	A highly complex project which may involve significant risks over and above those associated with the procedure	Consent must be obtained at least 5 to 7 days prior to surgery and anesthesia	A phase 3 clinical trial A high-risk procedure or drug considered experimental in nature

HSS = Hospital for Special Surgery.

The implications of the present study may not extend to clinical anesthesia research trials that pose moderate or substantial potential risk to the study patient. In such instances, initiating the consent process on the day of surgery may not be judged acceptable. In fact, the Anesthesia Research Committee at our institution, charged with supervising our department's research endeavors, has set forth guidelines (Table 6) for the timing of consent according to the complexity and risk of the proposed trial. These guidelines are indeed arbitrary and the subject of worthwhile future investigation.

In summary, the results of our study suggest that a preadmission telephone call on the day before surgery to initiate the consent process for a minimal-risk clinical anesthesia research trial does not improve satisfaction among consenting patients regarding the consent process compared to the traditional practice of initiating consent in hospital on the same day as surgery. Moreover, our study demonstrates that a preadmission telephone call on the day before surgery can be an impractical method to initiate the consent process for a clinical anesthesia trial.

Appendix I: Telephone Script

Hello. My name is Jane Lipnitsky from the Department of Anesthesia at the Hospital for Special Surgery. You are scheduled for shoulder surgery tomorrow, and I'm calling to tell you about an important study that our Department is conducting.

The anesthetic of choice for shoulder surgery at our hospital is a nerve block, meaning that we anesthetize the nerves that supply the shoulder with an injection of local anesthetic. There are two main techniques to locate the shoulder nerves for the injection: The first technique uses verbal feedback from the patient, and the second technique uses a small stimulating current. Both techniques are very safe and effective, and both techniques are commonly used by anesthesiologists at our hospital and around the world. Because both techniques are so highly successful and safe, we don't know for certain which technique is best. The point of our study is to answer—once and for all—which technique to locate the shoulder nerves is the very best for our patients.

If your anesthesiologist, whom you will meet tomorrow, decides that you are eligible for our study, he/she may ask you to participate. Your participation is completely voluntary. Your medical care will not be affected whether or not you choose to participate. If you do choose to participate, the technique used to locate your shoulder nerves will be determined at random—much like a coin toss.

There will be no inconvenience to you as a result of your participation, aside from a brief physical exam and few questions for you to answer while you are in hospital. If you choose not to participate, your anesthesiologist will select one of these two main techniques on your behalf.

Regardless of whether or not you choose to participate in our study, your anesthesiologist will answer your questions and discuss your options tomorrow before surgery.

Thank you for your time and we look forward to seeing you tomorrow.

Appendix II: Information Letter

Dear Sir/Madam,

You have recently been asked to participate in one of our important anesthesia research studies currently underway at the Department of Anesthesia at the Hospital for Special Surgery.

We are writing to find out how you felt about the research procedures at the Hospital for Special Surgery. We ask that you kindly complete this short questionnaire (attached) and return it in the self-addressed, stamped envelope provided.

There will be no inconvenience or risk to you from completing this questionnaire, aside from the 5–10 minutes which are needed to answer the questionnaire. The results from this questionnaire may not benefit you directly; however, the knowledge gained will help us with future patients.

Your responses to this questionnaire will remain confidential. Any reports or publications resulting from this research will not contain information which identifies you or any other patient in this study.

You may choose not to complete this questionnaire without affecting your future medical care. In no way does completing this questionnaire waive your legal rights nor does it relieve the investigators or involved institution from their legal and professional responsibilities.

If you have any questions about this questionnaire, you may call Dr. Jacques YaDeau at (212) 606–1206. If you would like to discuss your rights as a research subject and/or your participation in this study with an institutional

representative, you can call the Administrator, Institutional Research Board at (212) 774–2456.

Thank you for your cooperation.

Sincerely,

Jacques T. YaDeau, MD, PhD
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