What Determines Patient’s Decision to Participate in Clinical Anesthesia Research?

About this questionnaire
This questionnaire has been given to you because you have agreed to take part in a research study evaluating the factors that influence your participation in clinical research study. The general purpose of the study is to (1) understand individuals’ attitudes about clinical research and (2) to see if there are factors that affect people decision to participate or not participate in clinical trials.

What we will do with the data
The information you provide will be kept confidential and will not be linked to your name or your medical records. Do not write your name anywhere on this survey. We are collecting this information anonymously. These data will be used only to evaluate the significant factors affecting the consent process for clinical research studies. The results of the analysis on the collected information may be published, but at no time will you be identified.

In case of difficulty
If you have questions while completing the questionnaire, please contact:
Narai Balajonda, MD at balaj002@mc.duke.edu
phone number: 919-681-4377 / pager #919-970-7342

When you have finished completing the questionnaire, please return it in a sealed envelope to your nurse or any research staff.

Thank you for sharing your time, views and experience.
I. For each of the questions, please mark X in the box or fill in the blank, as appropriate:

1. Age: ___________ (years)

2. Gender  
   Male □  
   Female □

3. Ethnic origin:  
   White □  
   African American □  
   Hispanic □  
   Asian □  
   American Indian □  
   Other: ______ □

4. Years of education: ___________ (years) (e.g. if high school completed, then 12 years)

5. Marital Status:  
   Single □  
   Married □  
   Widowed □  
   Separated □  
   Divorced □

6. Religion:  
   Christian □  
   Muslim □  
   Buddhist □  
   Atheist □  
   Other □

7. Annual income:  
   Less than $25,000- □  
   $25,000-34,999 □  
   $35,000-49,999 □  
   $50,000-74,999 □  
   $75,000-99,999 □  
   $100,000+ □

8. In general, would you say your health is:  
   Excellent □  
   Very good □  
   Good □  
   Fair □  
   Poor □

9. How anxious do you feel at this moment? Place a mark (l) across the horizontal line, which best describes how anxious you feel right now.

   Not all Anxious | Extremely Anxious

10. Have you participated in clinical research before?  
    YES □  
    NO □
11. Before you were asked to complete this questionnaire, you were initially approached to participate in a clinical research study. Please indicate whether you decided to give your consent or not for this clinical research:

Yes, I consented to the clinical study

☐ 1

No, I did not consent

☐ 2

II. With respect to your experience when you were approached to participate in clinical research study, please indicate the extent to which you agree or disagree:

Please mark an X in the box that best describes your answer:

<table>
<thead>
<tr>
<th></th>
<th>Not at all</th>
<th>A Little Bit</th>
<th>Moderately</th>
<th>Quite a bit</th>
<th>Extremely</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. The researcher put me at ease</td>
<td>□ 1</td>
<td>□ 2</td>
<td>□ 3</td>
<td>□ 4</td>
<td>□ 5</td>
</tr>
<tr>
<td>2. I understood the purpose of the study</td>
<td>□ 1</td>
<td>□ 2</td>
<td>□ 3</td>
<td>□ 4</td>
<td>□ 5</td>
</tr>
<tr>
<td>3. The study was explained well by the researcher</td>
<td>□ 1</td>
<td>□ 2</td>
<td>□ 3</td>
<td>□ 4</td>
<td>□ 5</td>
</tr>
<tr>
<td>4. I felt pressured by the researcher</td>
<td>□ 1</td>
<td>□ 2</td>
<td>□ 3</td>
<td>□ 4</td>
<td>□ 5</td>
</tr>
<tr>
<td>5. There was potential benefit to me by participating</td>
<td>□ 1</td>
<td>□ 2</td>
<td>□ 3</td>
<td>□ 4</td>
<td>□ 5</td>
</tr>
<tr>
<td>6. The research made me more anxious</td>
<td>□ 1</td>
<td>□ 2</td>
<td>□ 3</td>
<td>□ 4</td>
<td>□ 5</td>
</tr>
<tr>
<td>7. The study would improve health care in the future</td>
<td>□ 1</td>
<td>□ 2</td>
<td>□ 3</td>
<td>□ 4</td>
<td>□ 5</td>
</tr>
<tr>
<td>8. My current health status influenced my decision</td>
<td>□ 1</td>
<td>□ 2</td>
<td>□ 3</td>
<td>□ 4</td>
<td>□ 5</td>
</tr>
<tr>
<td>9. To participate in the study was my only option</td>
<td>□ 1</td>
<td>□ 2</td>
<td>□ 3</td>
<td>□ 4</td>
<td>□ 5</td>
</tr>
</tbody>
</table>
With respect to your experience when you were approached to participate in clinical research study, please indicate the extent to which you agree or disagree:
Please mark an X in the box that best describes your answer:

<table>
<thead>
<tr>
<th>10. I was approached to participate at an appropriate time</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>11. I did not think I would receive any benefit from participating in the study</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
</table>

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<thead>
<tr>
<th>12. I had enough time to make a decision</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
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<tr>
<th>13. There was sufficient privacy when I was approached</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
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<thead>
<tr>
<th>14. I was worried about the potential risks</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
</table>

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<thead>
<tr>
<th>15. I do trust the study doctor’s motives</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
</table>

Is the study comparing 2 drugs, procedures or devices?

Yes: Go to #16.

No: check this box and go to #17.

16. I was worried that I would not get the investigational drug or procedure | 1 | 2 | 3 | 4 | 5 |

<table>
<thead>
<tr>
<th>17. I did not want to return for research-related follow-up</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
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<thead>
<tr>
<th>18. I was worried about the additional needle sticks required for the study</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
</table>

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<tr>
<th>19. I was worried about the additional amount of blood needed for the study</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
</table>
20. The financial compensation provided was too little

III. Please mark an X in the box that best describes your feeling today:

A. 

1. I am worried about the anesthesia

2. The anesthesia is on my mind continually

3. I would like to know as much as possible about the anesthesia

4. I am worried about the procedure

5. The procedure is on my mind continually

6. I would like to know as much as possible about the procedure

B. Your final decision to participate or not to participate was most influenced by:

(Choose only one answer)

_____ family members / friends’ opinion       _____ inconvenience
_____ my surgeon                           _____ fear
_____ way study was presented             _____ my religious beliefs/ convictions
_____ my trust in Duke                    _____ lack of trust
_____ financial compensation              _____ wrong timing
_____ my present health status             _____ prefers standard of care
_____ I made the decision by myself       _____ other:

_____ possibility of getting no treatment with placebo
C. Over the **last 2 weeks**, how often have you been bothered by any of the following problems?

<table>
<thead>
<tr>
<th>Problem</th>
<th>Not at all</th>
<th>Several days</th>
<th>More than nearly half the days</th>
<th>Everyday</th>
</tr>
</thead>
<tbody>
<tr>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
</tbody>
</table>

1. Little interest or pleasure in doing things

2. Feeling down, depressed, or hopeless

3. Trouble falling or staying asleep, or sleeping too much

4. Feeling tired or having little energy

5. Poor appetite or overeating

6. Feeling bad about yourself, or that you are a failure, or have let yourself or your family down

7. Trouble concentrating on things, such as reading the newspaper or watching television

8. Moving or speaking so slowly that other people could have noticed. Or the opposite—being so fidgety or restless that you have been moving around a lot more than usual

9. Thoughts that you would be better off dead, or thoughts of hurting yourself in some way