

ANESTHESIA AWARENESS REGISTRY

Eligibility Requirements Cover Sheet

The goal of this Registry is to study general anesthetics where the patient was aware of events occurring during surgery. Follow these steps to determine your eligibility for this Registry of awareness during general anesthesia.

STEP 1: Are you 18 years or older?

- Yes, I am 18 years or older.
You are eligible for this Registry. Continue to Step 2.
- No, I am under 18 years of age.
You are not eligible for this Registry. We can only survey patients who are 18 years or older.

STEP 2: Did you have general anesthesia for your surgery?

- Yes, I had general anesthesia.
You are eligible for this Registry. Continue to Step 3.
- No, I did not have general anesthesia.
You are not eligible for this Registry. Our Registry can only examine surgeries for general anesthesia.. Awareness of events will occur if general anesthesia was not administered. The Anesthesia Awareness Registry website, www.awaredb.org, has more information.
- I'm not sure if I had general anesthesia.
Contact your anesthesiologist or the Anesthesia Awareness Registry Offices (206-616-2669) for help. Do not proceed to Step 4 until you know for sure you had general anesthesia.

STEP 3: Read the two-page Consent Form carefully. Sign and date where it asks for the "Subject's Signature"

STEP 4: Complete the one-page Enrollment Form.

STEP 5: Complete the six-page Anesthesia Awareness Registry Survey.

STEP 6: Mail these documents to the Anesthesia Awareness Registry.

- Signed and dated Consent Form
- Completed Enrollment Form & Anesthesia Awareness Registry Survey

Notice: We will send confirmation of receipt of these documents to the mailing address you listed on the Enrollment form. A copy of your signed Consent Form, co-signed by a researcher of the Registry will be mailed to this same address.

STEP 7: Medical Records.

- Some people will be requested to submit copies of their medical records. PLEASE DO NOT REQUEST COPIES OF MEDICAL RECORDS UNTIL REQUESTED BY RESEARCH STAFF. You may participate in this survey even if your medical records are not available.
- If you are asked for copies of your medical records, we will send you information on the specific records we request and the reimbursement procedures.

Anesthesia Awareness Registry
c/o Robin Bruchas, M.S.W., rbruchas@u.washington.edu
Anesthesiology, Box 356540, University of Washington, Seattle, WA 98195-6540

Please remember that we cannot guarantee the confidentiality of any information sent by e-mail.



Consent Form

Anesthesia Awareness Registry

Researchers

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Christopher D. Kent, MD	Assistant Professor, Anesthesiology	206-616-2669
Karen L. Posner, PhD	Research Professor, Anesthesiology	206-616-2669
Robin Bruchas, MSW	Research Coordinator, Anesthesiology	206-616-2669

Researcher's Statement

INTRODUCTION

We are asking you to be in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether to be in this study. Please read this form carefully. You may ask questions about what we will ask you to do, the risks, the benefits, your rights as a volunteer, or anything else about the research or this form that is not clear. When we have answered all of your questions, you can decide if you want to be in this study or not. This process is called "informed consent."

PURPOSE OF THE STUDY

We want to learn about factors that may be associated with awareness during general anesthesia. We will use a questionnaire to find out any memories patients have of their surgery. We also need information from medical records from patients who may have been awake during general anesthesia. We hope that the results of this study will help anesthesiologists care for patients better in the future.

STUDY PROCEDURES

If you choose to be in this study, we will ask you to complete a written survey. If you are requested to obtain copies of your medical records, you will be given 3 options for obtaining copies of your medical records: 1. You can request copies from the hospital/clinic and send them to us, 2. You can request the hospital/clinic to send the copies of the medical records directly to the Registry, 3. You can sign a HIPAA authorization to request researchers on the team to request copies of the medical records. You will have the opportunity to discuss your experiences by phone with a member of the study team for the Awareness Registry. The survey and optional discussion will ask you to describe any memories that you have of the procedure. It will also ask whether you were upset, if you told your doctor, and if you were satisfied with your care. You are free to not answer any question. We would also like to obtain the following information from your medical record: health status, medical conditions, medications, type of anesthesia used, type of surgery, monitoring information, age, and gender. All health information that we collect during the study will be kept as study data. If you are unable to obtain your medical records for the study, we will be asking you a brief set of demographic questions pertaining to your date of surgery.

RISKS, STRESS, OR DISCOMFORT

Although we will make every effort to keep your information confidential, no system for protecting your confidentiality can be completely secure. It is still possible that someone could find out you were in this study and could find out information about you. The survey may also bring up unpleasant memories. You may refuse to answer any of the questions in the survey or optional discussion. You can ask questions now and later by contacting Ms. Bruchas at 206-616-2669 or any other member of the research team.

We have obtained a Certificate of Confidentiality from the Federal Government. This Certificate is not an endorsement from the Federal Government for our research. Rather, a Certificate of Confidentiality protects your privacy by allowing us to refuse to release your name or other identifying information to anyone outside of the research project and institution, even by a court subpoena, except as described below. In the unlikely event of a federal audit, we may have to reveal your name but only to those authorized representatives. The Certificate of Confidentiality does **not** prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

BENEFITS OF THE STUDY

You will not directly benefit from taking part in this research. We hope that the results of this study will benefit future patients by preventing awareness during general anesthesia and helping patients if it does happen.

OTHER INFORMATION

Being in this study is voluntary. You may choose not to be in this study, and you may withdraw from the study at any time without penalty or loss of benefits to which you are otherwise entitled. Whether you choose to take part in the study, or choose

Consent Form (continued)

not to take part, will not affect your health care. Information about you is confidential. We will code your survey responses and medical information. The link between your name and the code will be kept in a secured location, separate from the study information. We will keep the link between your name and the code until January 2012, and then we will destroy the link. We will not pay you for being in this study. We will reimburse you for charges to obtain copies of your medical records up to \$500.

You may want to get an estimate of charges to make sure the costs will not exceed \$500 before you request copies of your medical records. An original receipt will be required for reimbursement.

Government or university staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm.

The link between your name and your study data will not be kept beyond January 2012. If you are eligible to participate in other studies before that time, we will contact you. You will be asked to sign a separate consent for any future studies and may choose not to participate at any time.

By law we must voluntarily release your name and other identifying information to the appropriate officials, if we find or suspect intent to harm yourself or others.

All study data will be confidential. We will not release study data or copies of your medical records to you once they have been given to us. The only document we will return to you is a copy of this consent form.

Signature of Researcher

Printed Name

Date

Subject's Statement

This study has been explained to me, and I voluntarily consent to participate. I have had an opportunity to ask questions. If I have questions about the research, I can ask one of the researchers listed above. If I have questions about my rights as a research subject, I may call the University of Washington Human Subjects Division at 206-543-0098. I give the researchers permission to use my medical records as described in this consent form. I will receive a copy of this consent form.

Subject's Signature

Printed Name

Date

Copies to: Subject, Researcher's file

Enrollment Form

Anesthesia Awareness Registry

Please fill out this contact information so we may send you confirmation of receipt of your documents and send you your copy of the signed consent form. We may use this information to contact you if we need further information concerning your care.

The Anesthesia Awareness Registry will only use this contact information for correspondence that is directly related to the research for this Registry. We will not share or sell this contact information to any other party, company or research organization.

Patient's Address for Correspondence	
Name:	_____
Mailing Address	_____

Phone numbers	
Daytime: (____) _____ - _____	<input type="checkbox"/> Preferred
Evening: (____) _____ - _____	<input type="checkbox"/> Preferred
Cell: (____) _____ - _____	<input type="checkbox"/> Preferred
Best time to call:	_____
E-mail Address	_____
<p><i>Please remember that we cannot guarantee the confidentiality of any information sent by e-mail.</i></p>	

Anesthesia Awareness Registry Survey

Today's date _____

In this first section, we would like to collect some general information about your surgery and some specific details about your anesthesia experience.

1. What was your surgical procedure? _____
2. In what month and year did you have your surgery? _____
3. Did you stay overnight at the hospital AFTER your surgery?
 Yes
 No
4. Did any of your doctors mention the possibility of awareness during general anesthesia BEFORE you had your surgery?
 Yes
 No
 I don't remember
5. What is the last thing you remember before going to sleep? Please describe.

6. What is the first thing you remember when waking up after the procedure or surgery? Please describe.

7. What do you remember between going to sleep and the end of the surgery? Please describe in detail

Do you recall any of these things during your surgery? *Check all that apply.*

Feeling something in your mouth or your throat?

Yes No

Feeling unable to move, as if you were paralyzed?

Yes No

Feeling pressure or tugging near your surgery site?

Yes No

Feeling burning sensation near your surgery site?

Yes No

Feeling burning sensation NOT near your surgery site?

Yes No

Feeling pain near your surgery site?

Yes No

Feeling pain NOT near your surgery site?

Yes No

Feeling anxious or fearful?

Yes No

Feeling panic?

Yes No

Any other feelings?

Yes No

Please describe anything you felt: (physical or emotional)

Do you recall any of these other things during your surgery? *Check all that apply.*

Hearing people talking? Yes No

Any other sounds? Please describe what you heard:

Seeing light or lights? Yes No
 Please describe what you saw:

Did you dream or have nightmares? Yes No
 Please describe your dreams or nightmares:

Tasting or smelling things? Yes No
Any other experiences?
 Please describe in detail, including any conscious memories
 or anything else you felt, heard, or were thinking.

8. Which of the following statements best describes the timing of the events you have described?

- These events occurred before surgery had started.
- These events occurred as surgery was just starting.
- These events occurred in the middle of surgery.
- These events occurred when surgery was over.
- Not sure when these events happened.
- Other (specify) _____

Next we would like to ask you a set of questions about any past discussions you might have had about what happened to you during surgery.

9. Have you told anyone about your experience during your surgery? (Check all that apply.)

	Yes	No	When did you tell them?	How did they respond? If they provided an explanation, what did they tell you?
Family	<input type="checkbox"/>	<input type="checkbox"/>		
Friend(s)	<input type="checkbox"/>	<input type="checkbox"/>		
Anesthesia Provider	<input type="checkbox"/>	<input type="checkbox"/>		
Surgeon	<input type="checkbox"/>	<input type="checkbox"/>		
Nurse(s)	<input type="checkbox"/>	<input type="checkbox"/>		
Other(s)	<input type="checkbox"/>	<input type="checkbox"/>		

10. If your anesthesia provider, surgeon, or nurse offered you an explanation for what happened to you during anesthesia, do you believe the explanation is correct? Yes No If not, what do you think happened?

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11. Did any of the following people talk to you about your anesthesia awareness experience without being asked first by you?

(Check all that apply.)

- My anesthesia provider
- My surgeon
- Nurses
- Others (specify) _____
- None of the above.

12. To your knowledge, are your anesthesia provider or surgeon aware of your experience during surgery?

- Both are aware of my experience during surgery.
- Only my anesthesia provider is aware of my experience.
- Only my surgeon is aware of my experience.
- To my knowledge, neither my anesthesia provider nor my surgeon is aware of my experience. (SKIP TO QUESTION 16)

13. Has your anesthesia provider or your surgeon expressed concern about your experience?

- Both have expressed concern about my experience.
- Only my anesthesia provider has expressed concern.
- Only my surgeon has expressed concern.
- Neither my anesthesia provider nor my surgeon has expressed concern.

14. Did the doctors or hospital offer to investigate?

- Yes
- No (SKIP TO QUESTION 16)

15. If yes, were you or your family ever informed of the outcome of that investigation?

- Yes
- No

In this next section, we would like to learn about your feelings since your surgery.

16. In the time since your surgery, have you ever had any of the following feelings or experiences related to your anesthesia awareness experience?

	Yes I have. This feeling occurred approximately...				No, I never felt this.	Don't know/unsure	I prefer not to answer
	Daily	Weekly	Monthly	Less than once a month			
Anxiety/nervousness	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Chronic fear/phobias	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Avoiding crowds or noise	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Dreams or nightmares	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Flashbacks	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Short term memory loss	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Trouble sleeping	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Increased fatigue	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Depression	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

17. Do you *STILL* have any of these feelings or experiences?

	No, the feeling or experience went away in...				Yes, the feeling or experience still persists.	Don't know/unsure	I prefer not to answer
	0-3 months after surgery	3-6 months after surgery	7-12 months after surgery	13+ months after surgery			
Anxiety/nervousness	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Chronic fear/phobias	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Avoiding crowds or noise	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Dreams or nightmares	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Flashbacks	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Short term memory loss	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Trouble sleeping	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Increased fatigue	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Depression	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

18. Have any of the following been harmed as a result of your experience?

	Yes	No	Don't know	I prefer not to answer
My family relationships	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
My job performance	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
My friendships	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

19. Check all of the following statements that might reflect your current feelings about future surgeries?

- I will have another surgery if it is necessary for my health.
- I will not have another surgery, unless my life depended on it.
- I will not have another surgery on the same part of my body.
- I will not have another surgery at the same hospital.
- I will not have another surgery with the same surgeon.
- I will not have another surgery with the same anesthesia provider.
- I will not have another surgery with the same anesthetic.
- I will not have another surgery, unless I can have brain activity / function monitoring during surgery.
- I will never have another surgery.

20. How satisfied are you with the manner in which your concerns about your anesthesia experience were addressed by:

	Very satisfied	Somewhat satisfied	Somewhat unsatisfied	Very unsatisfied
Your anesthesia provider	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Your surgeon	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Your nurses	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Others _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

21. What might have been done differently to address your concerns after your anesthesia awareness experience?

22. Immediately after your surgery, which statement best describes your feelings?

- I was very upset.
- I was upset.
- I was slightly upset.
- I was not at all upset.

23. Today, which statement best describes your feelings?

- I am very upset.
- I am upset.
- I am slightly upset.
- I am not at all upset.

24. If you were upset about your anesthesia awareness experience in the past, but are no longer upset about it, when and why did your feelings change?

