

American Society of Anesthesiologists
Postoperative Visual Loss Registry

Packet for Patients
Submitting Your Medical Records

ASA Postoperative Visual Loss Registry

Packet for Patients Submitting Blinded Medical Records

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Sponsored by the Committee on Professional Liability, American Society of Anesthesiologists (ASA)

ASA Postoperative Visual Loss Registry

Instructions for Submitting Blinded Medical Records

SHOULD I REPORT MY CASE?

- 1. Did you suffer partial or total loss of eyesight within 7 days following *non-eye* surgery?**
 - ◆ We are collecting cases of partial or total loss of eyesight. This includes changes in the way you see, such as blurred vision, not being able to see as broad an area as before, not being able to see colors, things looking darker, or a need for stronger eyeglasses. It could effect one eye or both eyes. One eye might have different problems than the other eye.
 - ◆ We are collecting cases of vision problems noticed within 7 days after non-eye surgery. If the changes in your vision occurred within 7 days after an operation on a part of your body other than your eyes, we can collect your case. If the changes in your vision occurred after eye surgery, such as cataract surgery or lens implant, we cannot add your case to the study.
- 2. Do you have copies of your medical records?**
 - ◆ If not, are you willing to obtain copies of your records and send them to the Postoperative Visual Loss Registry Coordinating Center? We need many details from your medical records to add to our database. We will need copies of records from your surgery, such as your anesthesia record, your recovery room or intensive care unit (ICU) record, and the eye doctor's reports from the exams that were done to diagnose and treat your eye problems after surgery.

STEPS FOR SUBMITTING YOUR MEDICAL RECORDS

A "To Do" list is provided for your use on page 4.

- 1. Read the enclosed *University of Washington Information Statement* (page 5)**
- 2. Make a *Study Identification Code* (page 7)**

We will not be able to identify you from this study code. We use this code to make sure we don't receive the same case twice.
- 3. Complete the *Patient Registration and Acknowledgement Form* (page 8)**

Print legibly or type the requested identifying information for the person submitting the records. *This information will be separated from the records when we receive it.* This identifying information will be used to acknowledge receipt of the case materials, to send you back a copy of the signed informed consent document, and to create a mailing list for contacting participants in the future.

Steps are continued on the next page...

4. Request copies of your medical records

If you already have a copy of your medical records, skip this step.

The Postoperative Visual Loss Registry needs copies of these medical records

- ◆ *Surgeon's operative report from the surgery associated with your visual loss*
- ◆ *Anesthesia record from your surgery*
- ◆ *Postoperative recovery room record from your surgery*
- ◆ *If you went to the ICU, we will need the ICU record.*
- ◆ *Progress notes from your hospital stay*
- ◆ *Ophthalmologist (eye doctor) records from the first examination after your visual loss symptoms were noted*
- ◆ *Ophthalmologist records from any follow-up examination of your loss of vision*

If you have not yet obtained a copy of your medical records, you will need to get these from your health care providers (doctors and hospital). Your providers will have their own release forms that you will need to sign in order to obtain copies of your records.

5. Make sure that the copies of all medical records are blinded

All medical records submitted to the ASA Postoperative Visual Loss Registry must have all patient, provider, hospital and clinic names **obscured** (use white-out or black marker).

6. Please be sure all photocopies are *readable* (not too dark or too light).

Please send *copies* of your records, not the original records.
We will not be able to return these records to you.

7. Mail the completed case report packet and blinded *copies* of medical records to the Registry Coordinating Center:

ASA Postoperative Visual Loss Registry Coordinating Center

c/o Karen Posner, Ph.D.
Department of Anesthesiology and Pain Medicine
University of Washington
Box 356540
Seattle, WA 98195-6540

NEED HELP ON SUBMITTING YOUR MEDICAL RECORDS?

Questions about submission of medical records, case reports or study procedures should be addressed to Dr. Karen Posner at the address listed above

Dr. Posner can also be contacted by:

telephone (206-616-2630)
FAX (206-543-2958)
electronic mail posner@u.washington.edu

Please note that we cannot guarantee the confidentiality of any information sent via e-mail.

ASA Postoperative Visual Loss Registry

"To Do" List

- University of Washington Information Statement** (page 5)

DOCUMENTS THAT NEED TO BE SUBMITTED TO THE REGISTRY

- Completed study Identification Code** (page 7)
- Completed Patient Registration and Acknowledgement Form** (page 8)
- Obtain copies of your medical records:**
 - ◆ *Surgeon's operative report from the surgery associated with your visual loss*
 - ◆ *Anesthesia record from your surgery*
 - ◆ *Postoperative recovery room record from your surgery*
 - ◆ *If you went to the ICU, we will need the ICU record.*
 - ◆ *Progress notes from your hospital stay*
 - ◆ *Ophthalmologist (eye doctor) records from the first examination after your visual loss symptoms were noted*
 - ◆ *Ophthalmologist records from any follow-up examination of your loss of vision*

- Blind the copies of your medical records:**

Use white-out or black marker to obscure all references to the patient's name, care provider, hospital and clinic names on your copies of the medical records.

- Mail these documents to:**

ASA Postoperative Visual Loss Registry Coordinating Center
c/o Karen Posner, Ph.D.
Department of Anesthesiology and Pain Medicine
University of Washington
Box 356540
Seattle, WA 98195-6540

University Of Washington Information Statement Postoperative Visual Loss Registry

INVESTIGATORS

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INVESTIGATORS' STATEMENT

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 or not to be in the study. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When all your questions have been answered, you can decide if you want to be in the study or not. This process is called 'informed consent.'

PURPOSE

We want to understand the risk factors that may contribute to blindness or visual loss after surgery. You can be in this study because you have visual loss, which is a very rare complication after surgery. There are no known causes for this loss of vision. We want to compare information from medical records of patients who have lost vision after surgery.

PROCEDURES

If you choose to be in this study, we would like to obtain information from your medical records. We would like you to send us information from your medical records that includes: pre-existing diseases you have (such as heart disease, high blood pressure, or diabetes); your age, weight, and height; the type of procedure you had and details about your surgery; any ophthalmologic consultations you had; the results of any special tests you had regarding your visual loss; and any follow-up exams or treatment you had for your visual loss. We want you to send us your medical record without your name, or any other information that will identify you. We will use only anonymous information from your medical record. When we receive your medical records, we will enter the information we need into a database.

RISKS, STRESS, OR DISCOMFORT

There are no physical risks involved in this study. We will obtain anonymous information from your medical record.

BENEFITS

You may not directly benefit from volunteering for information about you to be used for research. We hope the results of using information from the database registry for research will help us prevent the complication of visual loss in patient in the future.

OTHER INFORMATION

Taking part in this study is voluntary. You can stop at any time. Your decision to participate or not participate in this research study will not impact your care at your health institution. The anonymous case reports you send to us are not linked to your name. This data will be kept in a locked file cabinet at the University of Washington indefinitely and may be used in future research. If you have any questions, you can ask me now or later. If you have any questions about your rights as a research subject, you can call the University of Washington Human Subjects Division (206) 543-0098.

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Study Identification Code

ANONYMITY OF CASE REPORTS

Each case will have a unique *coded* study identifier to make sure we don't receive the same case twice. We will not be able to identify you, your doctors, or your hospital from this study code. We need you to follow the directions to make your study code. We can't make this code because you will black or white out the names on your medical records before you send them to us.

CREATE AN 8-DIGIT STUDY IDENTIFICATION CODE

First letter of your last name. Example: <u>C</u>AMPOS								
Month of surgery (01-12). Example: <u>01</u>/21/99								
Day of birth (01-31). Example: 07/<u>09</u>/67								
Last 2 letters of the city where you had your surgery. Example: SEAT<u>LE</u>								
First letter of your surgeon's specialty (cardiac, orthopedics, neurosurgery, vascular surgery, urology, etc.) Example: <u>N</u>EUROSURGERY								
C	0	1	0	9	L	E	N	Example Study Code
								← Enter Your Study Code Here

SUBMIT THIS SHEET WITH THE MEDICAL RECORDS

Refer to pages 2 and 3 for instructions on submitting all the documents together.

ASA Postoperative Visual Loss Registry

Patient Registry and Acknowledgement

ACKNOWLEDGE YOUR PARTICIPATION IN THE STUDY

When your case is received by the ASA Postoperative Visual Loss Registry Coordinating Center, this sheet will be detached from the case so that it will *not be possible to identify the source of any individual case report*. This identifying information will be used to acknowledge receipt of the case materials, to send you back a copy of the signed informed consent document, and to create a mailing list for contacting participants in the future.

Your Name: _____

Your Complete Mailing Address: _____

Telephone Number (optional): _____