

**Neurologic Injury after Non-Supine Shoulder Surgery Registry
Packet for Providers Submitting Case Reports**

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Neurologic Injury after Non-Supine Shoulder Surgery Registry

Provider Registry and Acknowledgement

Acknowledge Your Participation in the Study

When the patient's case is received by the Neurologic Injury after Non-Supine Shoulder Registry 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. The identifying information will be used to acknowledge receipt of the case materials and to create a mailing list for contacting participants in the future.

Your (the provider's) Name: _____

Your Complete Mailing Address:

Telephone number (optional): _____

Instructions for the Neurologic Injury after Non-Supine Shoulder Surgery (NINS) Registry

Criteria for Case Reporting: Cases must meet *all* of the following criteria to be eligible for this study:

- Shoulder surgery in the non-supine position
- Any case of new central (brain or spinal cord) neurological injury after that occurs within 24 hours of surgery
- Patient age \geq 12 years

Exclusion Criteria:

- Any case where direct surgical trauma could cause cerebral or spinal cord injury
- Perioperative cardiac arrest, intraoperative hypoxic events or uncontrolled surgical hemorrhage
- Lack of adequate medical records including preoperative history and exam, anesthetic record, and postoperative follow-up and studies

Case Report Submission: Print legibly or type the requested identifying information for the person submitting the case report. *This information will be separated from the case report form.* It will be used only for creation of a mailing list for contacting participants if necessary. Case report forms should *not* contain names of patients, physicians, hospitals, or any other health care entities. Completed case report forms should be sent to the Registry Coordinating Office:

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

Questions about submission of case reports or study procedures should be addressed to Dr. Posner at the above address. Dr. Posner can also be contacted by telephone (206-616-2630), FAX (206-543-2958) or electronic mail (posner@uw.edu). Please note that we cannot guarantee the confidentiality of any information sent via e-mail.

Confidentiality of Case Reports: Each case report will have a unique *coded* study identifier for the purpose of detecting duplicate submission of case reports; this coded study ID will not enable the research team to identify the source of the case report or persons or institutions involved in the case.

IRB (Human Subjects) Review: The procedures for coordination of the NINS Registry have been reviewed and approved by the University of Washington Human Subjects Review Committee. This approval includes collection of cases submitted without identification of patients or health care providers involved in the cases. If you are associated with an organization that requires review of research studies involving human subjects or confidential medical records, it is your responsibility to contact your institutional research review board regarding your submission of anonymous case reports to this Registry. If you have any

questions or need assistance, contact the Dr. Posner at the Registry Coordinating Office (see above for contact information).

HIPPA: Your institution may require that you obtain authorization from the patient before abstracting information for anonymous submission to NINS Registry. An Institution Review Board (IRB) or Privacy Board may waive this requirement if the use of protected health information for research involves no more than minimal risk to privacy and the research could not be practically conducted without such a waiver and access to the protected health information. If you have any questions or need assistance, contact Dr. Posner at the Registry Coordinating Office (see Page 3 for contact information).

Coded Study ID: Create an 7-digit case report identifier using the following algorithm (example below):

1	2	3	4	5	6	7	8
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<u>Digit</u>	<u>Information from Medical Record</u>
1	<u>First</u> letter of patient’s last name
2-3	<u>Month</u> of surgery (01-12)
4-5	<u>Day</u> of birth (01-31)
6-7	<u>Last 2 letters</u> of hospital city

Example of ID Creation

Medical Record Data		Algorithm	Output
Patient Name	Campos	<u>First</u> letter of patient’s last name	C
Date of Surgery	1/21/99	<u>Month</u> of surgery (01-12)	01
Date of Birth	7/19/66	<u>Day</u> of birth (01-31)	19
Hospital City	Seattle	<u>Last 2 letters</u> of hospital city	LE

Case Report ID						
C	0	1	1	9	L	E
<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>	<i>6</i>	<i>7</i>

Do *NOT* include any other identifying information (names of patients, care providers, hospitals, etc.) on the case report.

Sources of Information for the NINS Registry Case Report

Use any medical records, notes, narrative summaries, consultant reports, risk management or other available documents to complete the case report. The following instructions indicate the portions of the medical record in which the information for each section of the case report will most likely be located. Other sources of information (in addition to those listed) may be used to supplement the medical record in order to complete the case report.

Part 1 - Patient Information: Most of this information should be available in the preoperative history and physical or preanesthesia assessment record. Use other records as needed to complete this section.

Part 2 - Surgery and Anesthesia: Use the anesthesia record to complete this section. The surgeon's operative report and intraoperative nursing record may contain relevant information and should be consulted for any data that is not available from the anesthesia record.

Part 3 – Surgical Position: Most of this information should be contained in the anesthesia record, the surgeon's operative report, or the nurse's records.

Part 4 – Perioperative Clinical Course: This information should be contained in the anesthetic record. Use surgeon's and nurses records as needed.

Part 5 – Emergence from Anesthesia and Postoperative Course: Use progress notes, consultant notes, and pertinent radiologic/laboratory studies for this section, if available. If appropriate, refer to the PACU, ICU and floor nursing notes.

Part 6 - Narrative Summary: Please WRITE LEGIBLY or TYPE. Provide a succinct narrative of the events. Specify the sequence of events and details not included elsewhere on the form. Elaborate on symptoms, diagnoses, and theories regarding the cause of this patient's outcome.

PLEASE INCLUDE A LEGIBLE COPY OF THE ANESTHETIC RECORD IN WHICH ALL IDENTIFYING INFORMATION HAS BEEN REMOVED. IF YOU CANNOT SEND A DE-IDENTIFIED COPY OF THE ANESTHETIC RECORD, PLEASE COMPLETE THE SUPPLEMENTAL ANESTHESIA RECORD ABSTRACTION FORM AND INCLUDE IT WITH THIS REPORT.

SUPPLEMENTAL RECORDS FOR INCLUSION

(Recommended, but NOT required for participation in study)

If possible, please send the following de-identified items with your other materials:

- History and physical form
- Current medication list
- Surgeon's operative report
- Brain imaging reports
- Neurology consultation report
- Hospital discharge summary

ALL IDENTIFIABLE PATIENT INFORMATION (E.G. NAME, DOB, RECORD#) SHOULD BE EITHER BLACKED OUT OR CUT OUT PRIOR TO SENDING THE SUPPLEMENTAL RECORDS.