
INFORMED CONSENT TO PARTICIPATE IN CLINICAL RESEARCH REGISTRY

SOLAS[®] Spinal Surgery Registry: Prospective Clinical and Radiographic Outcomes Data Collection in Degenerative, Deformity and Trauma Patients

Sponsor: NuVasive[®], Inc.
Protocol Number: NUVA.REG1101
December 22, 2010

Principal Investigator:

SPINE  **MIDWEST**

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24-Hour Telephone Number:

PURPOSE & DESCRIPTION OF THE REGISTRY

This registry will obtain information about standard of care spinal surgery procedures. The data collected will be used to understand differences in the success of various spine surgical treatments in a wide variety of patients. Your participation is voluntary and you may refuse to take part in this registry at any time. The study staff will be available to answer questions before, during, and after the study.

Dr. Rodgers gets paid as a consultant of NuVasive to provide services such as education, product training, and a product development. He also gets royalties on percentages of sales (however, not including sales at affiliated institutions).

WHAT MAKES THIS DIFFERENT FROM THE USUAL TREATMENT?

The registry will collect information about your pain levels and quality of life (from questionnaires), physical condition, surgical procedure, post-surgical care, and radiographic imaging (CT scans, MRIs, and/or x-rays) — any assessments your spine doctor is already capturing. All questionnaires and x-rays collected are standard of care. If you do not agree to participate in the registry, your care plan will not change. You will be treated the same whether or not you decide to participate in the registry.

HOW LONG WILL I BE IN THIS REGISTRY?

You will be asked to be available for standard evaluations and x-rays before surgery and 6 weeks, 3 months, 6 months, 12 months, 24 months and then annually following surgery. This schedule may change based on your doctor's standard practice. If you give consent to participate in this registry your consent does not expire. You may withdraw your consent at any time without penalty. However, if you decide to stop participating in the registry, we encourage you to talk to your doctor first. Refusal to participate will not harm your relationship with those treating you or your relationship with this institution. Your doctor or the registry sponsor, NuVasive, may end the registry at any time. If this occurs, your doctor will continue to follow you for your medical care. An undetermined number of patients will be enrolled in this registry.

POSSIBLE SIDE EFFECTS, RISKS, AND DISCOMFORTS

Risks associated with observational data collection include the risk of loss of confidentiality. However, all personal identifiers will be removed from visibility in the registry by anyone other than your doctor and his/her staff. Only de-identified information is seen by other investigators and the sponsor or disclosed in reports or publications. Research may involve risks that are not currently known. New information that may affect your willingness to participate will be shared with you.

CONFIDENTIALITY

Your information will be kept confidential to the extent allowed by law. We cannot guarantee absolute confidentiality. Your research records may be inspected and/or copied by groups such as: the sponsor of this study and its associates, the Food and Drug Administration (FDA), and the IRB. Federal regulation gives you certain rights concerning the privacy of your health information.

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Researchers covered by this regulation are required to get your authorization (permission) to use and disclose (share with others) any health information that could identify you. You agree that you will not be able to access your research information during your participation in this research. If you sign this informed consent form, you are giving permission for the use and disclosure of your health information for purposes of this research study. You do not have to give this permission. However, if you do not, you will not be able to participate in the study. You can cancel this authorization at any time by writing to the study doctor. If you do, your participation in the study will end. Data collected prior to the cancellation may still be used. Information released to others may not be protected by federal law.

WHO TO CALL IF YOU HAVE QUESTIONS

For questions, concerns, or complaints about the registry or if you think you may have a research-related injury, contact your doctor at the telephone listed on page 1 of this document. This study was reviewed by Aspire Independent Review Board (IRB). An IRB reviews research to protect the rights and welfare of study participants. If you have problems, concerns, suggestions, questions or information about the study, and for information regarding research subject's rights, please call Aspire's Quality Assurance and Regulatory Compliance Department at 1-877-366-5414 (toll free). While Aspire IRB has approved this research, only you can decide if participation is the right choice for you.

SIGNATURE AND CONSENT TO BE IN THE REGISTRY

Your signature below means that you have read the above information about the **SOLAS® Spinal Surgery Registry: Prospective Clinical and Radiographic Outcomes Data Collection in Degenerative, Deformity, and Trauma Patients** and have had a chance to ask questions to help you understand what you will do as a participant in this registry. Your signature also means that you have been told that you can change your mind later if you want to. You will be given a signed and dated copy of this consent form. By signing this consent form, you are not giving up any of your legal rights. You understand that it is your responsibility to tell the doctor or staff about significant changes in your physical or mental health during your participation in the registry.

SIGNATURE OF PATIENT

DATE

PRINTED NAME OF PATIENT

I confirm that a copy of this consent form has been given to this person to read and that this person has been told about the registry. The contents of the consent form describing the registry has been discussed with this person. The patient's questions have been answered. I have watched this person sign the consent form.

SIGNATURE OF PERSON OBTAINING CONSENT

DATE

PRINTED NAME OF PERSON OBTAINING CONSENT

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PRINTED NAME OF PERSON OBTAINING CONSENT

Legally Authorized Representative (LAR) signature required only for decisionally impaired subjects, including comatose and traumatized subjects who have a caregiver who can provide legally effective consent for the subject.

Your signature below means that you have read the above new information about this registry and have asked the questions you currently have about the research. By signing below, you indicate that you give permission for the participant to take part in this research and have had the opportunity to ask questions and those questions have been answered.

LEGALLY AUTHORIZED REPRESENTATIVE RELATIONSHIP TO SUBJECT DATE

Witness signature required only for limited or non-readers, illiterate, hearing impaired and visually impaired subjects.

Your signature below indicates that you have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. You confirm that the individual has given consent freely.

WITNESS SIGNATURE

DATE

WITNESS PRINTED NAME