

Name:

Date of birth/national identity number



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Version 4

Declaration of consent

For patients undergoing neck- or back surgery

The purpose of the Norwegian Registry for Spine Surgery is to improve the quality of treatment provided by hospitals in Norway. The registry collects information on neck- and back surgeries, including spinal deformities. The University Hospital of North Norway (UNN) is the data controller. The Norwegian Registry for Spine Surgery is consent-based and comply with the General Data Protection Regulation and regulation for medical quality registries.

What data are collected?

Your national identity number and name, information about the diagnosis, description about your medical condition, degree of disability and work status. In addition, your medical history, image findings and other details related to the treatment are registered, including the type of surgery performed.

How is the information collected?

Information is collected before and after surgery. Prior to surgery, the questionnaire that we now are asking you to fill out is registered, as well as information from your treating doctor. The Norwegian Registry for Spine Surgery will also send you a self-administered questionnaire, electronically via helsenorge.no or paper form by mail 3- and 12 months after the operation. If you have been operated for spine deformity, you will receive a questionnaire after 3 months, 2 and 5 years.

Who has access to your data?

It is of interest that those who have treated you (doctors and other health professionals) get access to their treatment results. They can then evaluate the effect of treatment offered in a systematic manner. Some of the information that is collected will therefore be made available to the hospital department or the institution that has treated you. This information is confidential and those who have access are obliged to not disclose any information. The information will also be compared with data from the Norwegian Patient Registry to calculate the NORspine's coverage rate.

Quality improvement and research

Health professionals and researchers working with quality improvement can request access to data from the registry to study public health, social welfare services and health economics. For quality and research projects, it could be relevant to merge data from the registry with information from your medical journal, or with other public registries (see attached list on the back of this paper). You can find an overview of the results, ongoing studies and publications from the registry in the annual reports that have been published on the registry's website.

See www.kvalitetsregistre.no for more information about the results of each hospital. If you consent that your information can be stored in the registry, you will be agreeing that you can be contacted outside the stated times (3- and 12 months after surgery), either by mail, telephone, video conference, SMS or e-mail. This means that you can be contacted several years from now. It is required by law that alignment of data needs approval by legal authorities. Research projects must be approved by the Regional Committee for Medical and Health Research Ethics. You may also be invited to participate in other research projects related to the registry. The research results can benefit future patients and will be published in Norwegian and international medical journals.

Data storage and your rights

The physical questionnaires will be archived at the hospital for a maximum time period of two years and will be shredded latest at the end of this time period. The information in the questionnaires are stored in an electronic database that is approved by the Data Protection Official, University Hospital of North Norway. The information in the database is stored in a secure manner that ensures personal privacy, and will be stored indefinitely. All data will be erased if the approval ends.

I have read through the information on both sides of this form, and agree that the mentioned information is registered and made available for quality assurance and research.

Place: _____

Date: _____

Signature _____

Turn the page!

It is optional to participate in the registry. If you do not give your consent, it will have no consequence for the treatment you receive now or in the future. You have the right to know what is written about you in the registry, you have the right to rectification and erasure of your personal data. If you change your mind and want to withdraw your consent, you can contact the registry secretary at the University Hospital of North Norway by email ryggregisteret@unn.no or by calling our phone number 776 69015.

You can also contact the Data Protection Official at the University Hospital of North Norway by email personvernombudet@unn.no if you need advice. If you believe that the health information is not managed in accordance with the regulations, you can contact the Norwegian Data Protection Authority (Datatilsynet) or the Norwegian Board of Health Supervision (Helsetilsynet).

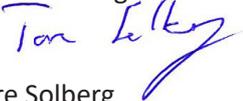
It could become relevant to merge information from the Norwegian Registry for Spine Surgery with the following public registries and population surveys:

- Other national medical quality registers, such as:
 - Norwegian neck and back register
 - The Norwegian Arthroplasty Register (NAR)
 - The National Paediatric Hip Register
- Registries in the Norwegian Labour and Welfare Administration (NAV)
- Norwegian Cause of Death Registry
- Medical Birth Registry of Norway
- Norwegian Patient Registry (NPR)
- Cancer Registry of Norway
- Norwegian Prescription Database (NorPD)
- Registries in Statistics Norway
- Population based surveys from Cohort of Norway
- Population based surveys from the National Health Screening Service (SHuS)
- Data from The Norwegian Tax Administration
- The National Population Register
- Norway Control and Payment of Health Reimbursement (KUHR) Database

It may also be relevant to align anonymised information from the Norwegian Registry for Spine Surgery with similar registries internationally:

- Sweden (Swespine)
- Denmark (DaneSpine)
- Finland (FINspine)
- Netherland (Dutch Spine Surgery Registry)
- European international spine registry (Spine Tango)
- Australia (Australian Spine Registry)

With best regards



Tore Solberg
Academic director, the Norwegian Registry for Spine Surgery