NordicSCIR
Nordic Spinal Cord Injury Registry

Patient information
Date of birth
Name

Consent form

Information and enquiry regarding consent to participate in the Nordic Spinal Cord Injury Registry, NordicSCIR.

Background
A spinal cord injury can have lasting consequences and result in a need for life-long follow-up. In the Nordic countries, the occurrence of spinal cord injuries (traumatic/non-traumatic) is relatively low. Denmark, Finland, Iceland, Sweden and Norway have special departments for rehabilitation and monitoring of patients with spinal cord injuries. In Norway, a national quality registry (NorSCIR) was set up for this patient group in 2011. The Nordic Council has asked the Norwegian Directorate of Health to initiate a pilot project with the purpose of establishing a Nordic Spinal Cord Injury Registry. In 2015 the Nordic Spinal Cord Injury Registry was granted a licence by the Norwegian Data Inspectorate to process health-related data. Data-processing responsibility for the registry has been placed with St Olav's Hospital in Trondheim, Norway. Given that the officer in charge of data processing is in Norway, the collection and processing of data is subject to Norwegian legislation, irrespective of regulatory controls in the other Nordic countries.

Purpose
One fundamental purpose of a Nordic Spinal Cord Injury Registry is to improve the quality of spinal cord injury treatment. For a long time now, the professional environment in participating countries has held a fervent wish to set up a Nordic Spinal Cord Injury Registry. The registry will be instrumental in creating an adequate patient basis for gathering structured, quality-assured data on the occurrence, medical treatment and rehabilitation of people with a spinal cord injury. Variables for use in the registry are based on data sets from ISCoS, the International Spinal Cord Society. These are firmly anchored in the relevant specialist environment.

These data will form the basis for:
- increased knowledge
- quality assurance
- development and follow-up of quality indicators
- research cutting across regional, national and international borders
- in addition, using the ISCoS data set will provide scope for comparing data with other countries worldwide, since these data sets are used in large parts of the world.

Where will the information be sourced?
The data included in the registry are based on information in your medical record, obtained by doctors and other healthcare staff, in connection with periods of admission related to primary hospital stays and later check-ups at hospital. You will also be asked to complete a form to provide information about your quality of life during your hospital stay.

What will be registered?
The registry will contain particulars such as year of birth, gender, injury date and treatment, and record information about injury-related consequences and results of examinations, measures and interventions necessary and relevant for this purpose. A record will also be made of the facility to which you are discharged on completion of your rehabilitation stay. New registrations will be made in connection with later periods of admission in the case of specialized rehabilitation. All information will be treated with respect for personal security and privacy, and in accordance with laws set out in regulations.

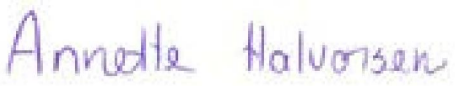
Who will have access to the information?
Information will be transferred from your treating hospital to your national register, if applicable, before being transferred in turn to the Nordic database. Here, all information will be stored in depersonalized and anonymized form. Data in the registry will be stored for as long as the registry is granted a licence. All data will be deleted if the licence is discontinued. The information gathered will be treated confidentially, which is to say that only people working on the registry can read it. Everyone with access to the registry is subject to a duty of confidentiality.

Research
The registry can be used to evaluate the importance of various factors for good or poor treatment results, or the bearing the treatment has on aspects of social medicine and health economics. In order to quality-assure the health services in this way, it is necessary to make use of research methods, sometimes as part of research projects. For such purposes, it may be relevant to cross-link information from the registries with central registers, including foreign ones (Nordic/EU countries). You may also be invited to take part in special research studies related to the purpose of the registry. All data compilation requires the prior approval of the public bodies required by law, for instance the Data Protection Official. The provision of data to research projects will be undertaken by the Nordic Steering Group for NordicSCIR. All information will be treated subject to personal security and privacy, and in accordance with current laws and regulations. Annual Nordic reports will be compiled from the registry. Results will also be published on a continuous basis at specialist meetings and in national and international medical journals. Results based on analyses from the registry will not be traceable back to individuals.

By consenting to take part in the Nordic Spinal Cord Injury Registry – NordicSCIR – you accept that information registered about you can be used for both quality assurance and research purposes, and you also consent to being contactable again outside of regular hospital check-ups.

Rights
Registering with this registry is voluntary, and in order for registration to take place, written consent must be given. If you do not wish to consent, this will not have any implications for the treatment you receive at the hospital / specialist health services. You are entitled to know what the registry says about you, and you can demand that information about you be deleted or corrected without stating a reason. You will find information on the registry at www.kvalitetsregistre.no, where you can also find information about how to request deletion or correction of information about you contained in the registry. There will also be information on the registry at the ward or department treating you.

With best wishes,



Annette Halvorsen (Steering Group Leader, NordicSCIR)

Consent to take part in the Nordic Spinal Cord Injury Registry – NordicSCIR

I have read through the information and give my consent for registration of the data referred to above and for making it available for quality assurance and research.

Place: **Date:** **Signature:**