

 HELSE BERGEN <small>Haukeland universitetssjukehus</small>	SOReg - Samtykkeskjema - engelsk
Kategori: Pasientbehandling/Pasientadministrasjon/Administrative rutiner	Gyldig fra/til:30.08.2024/30.08.2025
Organisasjon: Helse Bergen HF/Laboratorieklinikken/Avd. for medisinsk biokjemi og farmakologi	Versjon: 1.00
Godkjenner: Hege Hoff Skavøy	Skjema
Dok. ansvarlig: Villy Våge	Dok.id: D79122

Request for registration with the Scandinavian Obesity Surgery Registry – Norway (SOReg-N)

Background and purpose

We are asking for your consent to include you in the Scandinavian Obesity Surgery Registry – Norway (SOReg-N). The purpose of SOReg-N is to improve the quality of treatment for patients undergoing obesity surgery. By comparing the treatment and follow-up given to a large number of patients, the registry can provide a comprehensive picture of any changes in symptoms and blood values before and after an operation and of complications and side-effects of the treatment. This allows us to gain an overview of the long-term effects and quality of this treatment.

Inclusion in the Scandinavian Obesity Surgery Registry – Norway is voluntary. This means that you must sign a written consent form before we can include you in the registry.

The registry will hold the following information about you:

Your registry entry will contain your name, 11-digit national identification number, information about diagnoses and administered treatments. Other information held may include your socio-economic status, medication, blood values and the results of any urine tests. The information will be collected before your operation and when attending ordinary check-ups after your operation. You will also be asked questions regarding health-related quality of life issues before and after surgery, and your experiences as a patient in relation to follow-up with the healthcare system after the operation.

Helse Bergen HF is the registry's data controller. Your personal data is registered electronically and protected against unauthorised access.

The registry is licensed by the Norwegian Data Protection Authority, and the information is stored in compliance with the relevant permits. All the collected data is treated in confidence, and everyone working with the data must observe confidentiality in respect of the information they become party to.

Right of access, changes and deletion of personal data

You may request a copy of the information being held about you at any time, and you are entitled to have any errors in the register data corrected. You may at any time request your personal data to be deleted from the registry without having to give a reason. Deleting your personal data does not mean your data will be removed from anonymised research files that have already been used for research.

It will not have any bearing on your treatment if you choose not to register or if you decide to withdraw your consent at a later date.

Disclosure of data from the registry may be made to scientists and to a Nordic and possibly a European obesity surgery registry, but then only in the form of an disidentified summary. This means that all your information will be processed without your name, national identity number and other directly identifiable data. A code links you to your personal data and tests via a name register. Only authorised personnel associated with the registry have access to the name register and can identify you.

Following your operation, if you are followed up in a different hospital than the one where you had your operation, the registry will issue a reminder to register your follow-up information to the hospital in charge of collecting information for the registry after your operation. This reminder is not anonymised and will identify you by name.

For research purposes it may be relevant to collate information from the registry with other data from the hospital's patient records and from the following other registers: Norwegian Patient Registry, Cause of Death Registry, Norwegian Prescription Database, Medical Birth Registry, Cancer Registry of Norway and Statistics Norway. Checks against the Norwegian Patient Registry and the Norwegian Prescription Database will be performed regularly to measure coverage and validity.

Annual national reports will be produced by the registry. The results will be published at medical conferences and in national and international medical journals. Results based on analyses of the registry cannot be traced back to individual patients.

All research projects must obtain advance approval from the Regional Committee for Medical and Health Research Ethics (REC) and other public agencies as required by law. Once a project has been approved, you can find more information about it on the SOReg-N website:

<http://www.helse-bergen.no/soreg>

Registry co-ordinator / contact person: Scandinavian Obesity Surgery Registry – Norway, Villy Våge, Helse Bergen, PB 1400, 5021 Bergen. Tel: (+47) 90863744. Email: villy.vage@helse-bergen.no

Consent form – Patients older than 16	
Registry: Scandinavian Obesity Surgery Registry – Norway (SOReg-N)	Project number:
Name of registry co-ordinator: Villy Våge	Clinic/department: Helse Bergen HF
I have read the information letter "Request for registration with the Scandinavian Obesity Surgery Registry – Norway" and have familiarized myself with the purpose of the registry, which personal data will be registered, where the data is taken from, how the data will be disclosed, and what my rights are with regard to access, changes and deletion of data contained in the registry.	

I am aware that personal data will be obtained from my patient records. Collected data will only be used for quality assurance of treatments and for research into obesity.

I hereby consent to information about me being included in SOReg-N and for this information to be used for quality assurance and research into obesity.

Name (in block capitals):

National identity number (11 digits):

Date

Signature

To be completed by a registry representative

I confirm that I have provided information about SOReg-N.

Name (in block capitals):

Date

Signature

Additional comments:

Consent form – Children aged between 12 and 16

Registry:

Scandinavian Obesity Surgery Registry – Norway (SOReg-N)

Project number

Name of registry co-ordinator:

Villy Våge

Clinic/department: Helse Bergen HF

On behalf of the child, I have read and informed the child of the information letter “Request for registration with the Scandinavian Obesity Surgery Registry – Norway” and have familiarized myself with the purpose of the registry, which personal data will be registered, where the data is taken from, how the data will be disclosed, and what the child’s rights are with regard to access, changes and deletion of data contained in the registry.

Collected data and test results will only be used for quality assurance of treatments and for research into obesity.

On behalf of the child, I hereby consent to information about the child being included in SOReg-N and for this information to be used for quality assurance and research into obesity.

Name of the child (in block capitals)

National identity number (11 digits)

Date

Parent/guardian's signature

Role
(mother/father/guardian)

To be completed by a registry representative

I confirm that I have provided information about SOReg-N.

Name in block capitals

Date

Signature

Additional comments:

Visitors' address: Haukeland University Hospital, Lower Ground Floor, Armauer Hanssens Hus, Haukelandsveien 28
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Business registration no.: NO 983974724 mva. Website: <http://www.helse-bergen.no/soreg>