ST. OLAVS HOSPITAL
UNIVERSITETSSYKEHUSET I TRONDHEIM

Request for registration in the RevNatus registry

Background and goals

By this we ask your permission to enrol you in the quality register RevNatus.
By collecting data about you and your rheumatic disease related to pregnancy in a registry, we can use this data for quality improvement, to monitor treatment and care and to support further research related to pregnancy and rheumatic diseases.

Being enrolled in the registry is voluntary and requires written informed consent. This means that we may only include you in the registry after you have signed a consent form. The data will be stored electronically as long as necessary to ensure the goal of the registry, as above mentioned. By signing, you agree to let the information be used in future quality- and research projects on the topics of pregnancy and rheumatic diseases.

There will be up to seven registrations, starting prior to pregnancy and up to 1 year after delivery.

The registry will contain the following information on you:

Information that is included in the register is your name, personal identification number, address, education, work and civil status, diagnostic data, disease activity, medical treatment, nicotine usage, physical activity, self-reported health status, relevant pregnancy data and pregnancy outcome (including information about the new-born baby).

Data collection

The data will be collected using the medical journal and from your electronic self-reporting. St. Olavs hospital is in charge of the data handling of the registry. All registration is done using data technology and data may not be accessed by unauthorized persons.

Data handling

All collected information will be handled confidentially. St. Olavs hospital is in charge of the data handling and as such, will secure your privacy rights.

Access to personal information, and the right to correct or delete information

You may at any time be granted access to the information in the registry concerning yourself. Furthermore, you have the right to have corrected possible errors in your data and you may demand that all collected information on you is deleted from the registry without providing a cause for your wish. Anonymous data files which have already been used in research projects may however not be deleted. Whether you chose not to be included or if you decide to withdraw your consent, will not influence your treatment program. Should you wish to enforce your rights you may contact St. Olavs hospital by the registry leader.

Delivery of data from the registry will only be allowed when in agreement with the goal of the registry. Data will be delivered in the form of de-identified files. This means that information will be handled without identifiable data such as name, date of birth or other directly recognizable information. The department where you are treated can use de-identified files for quality improvement projects.

Merging data with other sources

In research- or quality projects it may be necessary to compile information from the registry to information from medical records, health surveys, or other registries. Furthermore, data from the registry may be used as part of large international research projects where the goal is to gain new knowledge regarding pregnancy and rheumatic diseases.

All research projects must be approved by the Regional Committees for medical and health research Ethics and other official authorities as claimed by the law.
Data may be compared to data in the Norwegian Patient Registry in order to evaluate data completeness and degree of coverage.

You might be asked at a later stage to give permission for us to gather further information regarding you and your health status, and the development of your baby. We will contact you if this becomes relevant, and we will need your consent.

Information concerning on-going research projects from RevNatus may be found at the web-site: www.stolav.no/revnatus

Contact information

You may find additional information about the registry at www.stolav.no/revnatus

If you have questions regarding your participation in the registry, you may contact registry leader: Hege Svean Koksvik, Norwegian National Advisory Unit on Pregnancy and Rheumatic Diseases (NKSR), St. Olavs hospital, phone number: 72 82 64 17

St. Olavs hospital has a data protection officer (personvernombud) who may give general advice concerning your privacy rights: personvernombudet@stolav.no, phone number: 72 57 30 00

You may complain to the Norwegian Data Protection Authority if your rights concerning your personal data protection has been violated.

Consent form	
Register RevNatus	
I have read the information form “Request for registration in the RevNatus registry» and I am aware of the aim of the registry, what data are registered, how data is collected and handled, and my rights concerning access to data, and the right to access personal information, and to correct or delete data from the registry.	
Name in block letters	Personal Identification Number (11 digits)
Date	Signature

It might become relevant to compile information from the registry with other registries or health surveys. More information regarding the background and aim of the relevant linking can be found on our webpage when applicable.

Registries and health surveys that RevNatus can be linked to:
Norwegian Arthritis Registry (NorArthritis)
Norwegian Vasculitis and biobank registry (NorVas)
Norwegian Register for Pediatric Rheumatology (NOBAREV)
Norwegian systemic connective tissue disease and vasculitis registry (NOSVAR)
Medical Birth Registry
Norwegian Registry of Pregnancy Termination
Norwegian Cause of Death Registry
Norsk register for biologiske legemidler (NOKBIL)
Norwegian Patient Registry
The Norwegian Renal Registry
FD-trygd
Norwegian Prescription Database (NorPD)
Norwegian Cardiovascular Disease Registry
The Trøndelag Health Study (HUNT)
The Tromsø Study with biobank
Biobank1
Vestnorsk biobank for Revmatologiske Sykdommer

It might become relevant to share anonymised information with international collaboration projects, such as:
European network of pregnancy registers in rheumatology (EuNep)
The Organization of Teratology Information Services registry study (OTIS)