NORSK VASKULITTREGISTER & BIOBANK

version 3.1

Patient Data (Bar Code)
National identity number
Name

NorVas Consent Form

Invitation to participate in the Norwegian Vasculitis Registry & Biobank (NorVas)

This letter is a request for you to participate in the Norwegian Vasculitis Registry & Biobank.
Below is information about what you agree to, and the purpose and terms of use of the Norwegian Vasculitis Registry & Biobank. Please read through this letter before signing your consent. You must keep a copy of this letter yourself. Participation is voluntary. If you choose not to participate, you do not need to give a reason, and this will not have any consequences for you now or in the future.

Background information

Vasculitis is a collective term for several rare and sometimes very severe diseases with autoimmune inflammation in blood vessels in the body. The clinical outlook and symptoms vary according to which blood vessels and which organs in the body are most affected.
The medical communities in rheumatology and renal medicine have established the Norwegian Vasculitis Registry, which is a medical quality registry for vasculitides. Its purpose is to improve the quality of diagnosis and treatment of these diseases. There is a need for better knowledge, not only about the diseases of each patient, but about this entire patient group. The information in the register will therefore also be used for research. Such a register could also help to map the need for assistance for this patient group, and form the basis for prioritising health services.

What should be registered in the registry?

The information included in the register is your national identity number and name, the ailments you experience, diagnosis and degree of disability. Ordinary medical record information such as medical history, examinations, diagnoses and information related to the treatment you have received is also recorded. For those persons who are given treatment with the new, so-called biological drugs, information relating to the treatment and any side effects of these drugs will also be registered in the Norwegian Quality Registry for Biological Treatment (NOKBIL).

Where will the information in the register be obtained from?

The information will be obtained from you as a patient and from your hospital records. This includes test results such as blood tests and x-rays. To assess the quality of treatment, we need information about you from before, during and after treatment. Before treatment, we ask that your fill in a form and that the doctor who treats you also fills out a form. In order to follow the course of the disease and the effect of the treatment, information will be collected at the same time as you attend check-ups at the hospital department that treats you. You may be asked to answer a questionnaire from the Registry at a later date, and you may be contacted at a later date for information about your illness.

What is biobank?

The biobank contains blood samples (DNA genetic material, serum, plasma, urine and tissue samples) from patients with vasculitis registered in the Vasculitis Registry. The sample material is stored and will be linked to registry information, which forms a unique basis for studying the possible hereditary factors for the emergence of vasculitides, and studies of possible disease-associated proteins or environmental exposures that may be significant. One will also be able to do analyses of DNA and serum related to disease course and treatment effect of medicines. It may be appropriate to send material for analysis abroad.

If you agree to participate in the study, you also consent to the biological material being included in the biobank and the analysis results kept in the corresponding register. The general manager of NORVAS at the Rheumatology section at UNN is responsible for the research biobank. The biological material may only be used after approval by the Regional Committee for Medical and Health Research Ethics (REK).

Who can access the data?

The information is stored in a separate data register approved by the Norwegian Data Protection Authority. Data in the register will be stored forever, but you can request that it be deleted if you later wish. The collected data is treated confidentially, i.e. only people who work with the register or have processed you can read it. Everyone who has access has a duty of confidentiality regarding what they learn through their work with the register. In order to assess the completeness of the register throughout Norway, it will be linked to the Norwegian Patient Registry.

Research

In order to quality assure the health service, it will be necessary to use research methods. Researchers will be able to use the register to evaluate, among other things, what is important for good or poor treatment outcomes, what significance the treatment has in relation to national insurance schemes, social medicine, and health economic conditions.

For special research projects and quality assurance of the register, it may be appropriate to link information from the register with other public registers. All such compilations require prior approval by the public bodies required by law. It may also be relevant to analyse de-identified samples from you abroad and to compare anonymised data from this Norwegian register with foreign registers.

In order to gain access to registry data and biobank material, researchers must apply for this to the steering group for the Norwegian Vasculitis Registry & Biobank. In addition, all research projects must be approved by the Regional Committee for Medical Research Ethics and, if applicable, the Norwegian Data Protection Authority. In research projects, only information that is necessary for analyses and evaluation of results will be delivered to persons responsible for studies.

The information will then only be marked with a register-specific number, and your identity will not be available. Results from research projects will be presented so that individuals cannot be identified or recognised. The consent also means that you can be contacted again by the Registry outside of hospital checks.

All information will be treated with respect for privacy and your private life, and in accordance with laws and regulations. For more information about the register, research projects and links to other registers, see the Registry's website: www.norvas.no.

Rights

Registration in this register is voluntary, and in order for registration to take place, written consent must be given. You have the right to know what is written about you in the register, and you can demand that information about you be deleted or corrected, in accordance with the Personal Data Act. You can also opt out of having samples stored in Biobank. If you later wish to withdraw or have questions about the study, you can contact the Norwegian Vasculitis Registry & Biobank at the Rheumatology Section, Department of Neurology, Dermatology and Rheumatology, University Hospital of Northern Norway Health Trust; E-mail: norvas@unn.no

Yours truly,

Synøve Kalstad
Head of NorVas

Consent to participate in the register

I have read through the information and agree that said information is recorded and made available and for quality assurance and research.

Patient's signature and date: _____

Proxy consent if required
(Signed by parent, guardian etc., date) _____

It may be appropriate to combine de-identified information about you from the register with the following registers and population surveys: (For more information see: www.kvalitetsregistre.no)

Norwegian Patient Registry / Prescription Database / Medical Birth Registry / Cause of Death Registry /Cancer Registry
Norwegian Cardiovascular Disease Registry
Norwegian Surveillance System for Communicable Diseases (MSIS) / Tuberculosis Registry
Norwegian Immunisation Registry (SYSVAK)
National Registry for Chronic Obstructive Pulmonary Disease (COPD) / Norwegian Renal Biopsy Registry
Norwegian Nephrology Registry
Norwegian Multiple Sclerosis Registry & Biobank / Norwegian Diabetes Registry for Adults
REVNATUS (Rheumatic diseases in pregnant women/neonatal period) / Norwegian Quality Registry for Biological Medicines (NOKBIL)
Norwegian Arthritis Registry (NORARTHRIT)
Child Rheumatism Registry (National Register for Arthritis and Autoimmune Connective Tissue Diseases in Children) / Norwegian Systemic Connective Tissue Disease and Vasculitis Registry
Northern Norway Vasculitis Registry / Registries at NAV - FD Trygd / The Directorate of Taxes databases / HUNT Biobank / Tromsø Study Biobank
Population surveys included in Conor (Cohort of Norway) / Population surveys included in the National Health Surveys (SHuS)

It may be appropriate to disclose anonymised information to international collaborative projects.
e.g.
DANBIO (Danish Biological Drug Registry) / ARTIS (Swedish Biological Drug Registry) / BSRBR (British Biological Drug Registry) / UKVAS (British Vasculitis Registry)
French Vasculitis Registry
The European Community Respiratory Health Survey (ECRHS) / Respiratory Health in Northern Europe (RHINE)