Invitation to the Norwegian MS Registry and Biobank

This letter is an invitation to be registered in the Norwegian MS Registry and Biobank. Below you can find information about what you give consent to and about the purpose of and conditions for use of the Norwegian MS Registry and Biobank. Please read this letter before you decide whether to sign the consent form. This letter and one copy of the consent form are for you to keep.

Participation is voluntary. If you do not wish to participate, you do not have to give any grounds for your decision, and it will have no consequences for you now or in future.

• If you have multiple sclerosis (MS), you will be asked to consent to registration of information in the Norwegian MS Registry and Biobank and to provide a blood sample and a cerebrospinal fluid sample (already collected in connection with the investigation of your condition) for studies of the occurrence and causes of MS.

• If you have multiple sclerosis and are already registered in the Norwegian MS Registry, you will be asked to consent to registration in the Norwegian MS Registry and Biobank by also providing a blood sample and a cerebrospinal fluid sample (already collected in connection with the investigation of your condition) for studies of the occurrence and causes of MS.

If there are words or information in this document that you find difficult to understand, please ask a neurologist at your neurology department or contact the Norwegian MS Registry and Biobank.

What is MS?

MS is an inflammatory disease that affects the nervous system (brain and spinal cord), and symptoms include paralysis, balance problems, and visual and sensory disturbances. The cause of MS is not known, but the disease is believed to be a result of an abnormal reaction to exposure to environmental factors (for example a viral infection) in people with a hereditary susceptibility. MS is not a hereditary disease in the normal sense of the word, but the risk of getting MS is slightly elevated (approx. 2%) if you have a close family member with MS.

What is the Norwegian MS Registry and Biobank?

The Norwegian MS Registry was established in 2001 under a licence issued by the Norwegian Data Protection Authority (1998/ 885-5) and funded by grants from the Ministry of Health and Social Affairs. The Registry is based at the Norwegian National Advisory Unit on Multiple Sclerosis, Department of Neurology, Haukeland University Hospital. The data registered include demographic data (name, address, date of birth and national ID suffix, place of birth, year of onset, year of diagnosis, who made the diagnosis and where); clinical data (onset symptoms, diagnostic procedure, diagnosis category, the course of the disease, family history of MS and clinical status) and treatment data (immunomodulatory treatment, type of medication, time of start-up, effect and side effects). The Registry also collects patient-reported data on quality of life related to the disease and treatment, including side effects and symptoms, as well as the patients' perception of the follow-up/treatment. Registration is subject to the informed written consent of each patient with MS.

In 2006, an MS biobank was established in connection with the Norwegian MS Registry, and the name of the new unit is the Norwegian Multiple Sclerosis Registry and Biobank. Its formation was approved by the Regional Committee for Medical and Health Research Ethics, the Norwegian Data Protection Authority, the Ministry of Health and Care Services and the Norwegian Directorate of Health. The biobank units contain blood samples (DNA and serum) and cerebrospinal fluid from patients with MS who are registered in the Norwegian MS Registry.

The samples are stored at the Norwegian Institute of Public Health in Oslo (DNA) and at Haukeland University Hospital's Department of Neurology in Bergen (serum and cerebrospinal fluid). All samples held by the biobank have been provided with the written consent of the donor.

Purpose of the Norwegian MS Registry and Biobank

The purpose of the MS Registry is to monitor the occurrence of MS in order to uncover geographical differences and any changes over time. This will provide a basis for studying MS with a focus on identifying its causes and planning health services for patients who suffer from the disease. The registration of the effect and side effects of immunotherapy for MS will form a basis for medical and socio-economic quality control of new and expensive treatment methods.

In the biobank units, biological material linked to registered information will provide a unique basis for studies of genetic susceptibility (for example DNA analysis of immune and myelin genes) as well as of possible disease-associated proteins or exposure to environmental factors in serum or cerebrospinal fluid (for example analysis of degraded proteins, virus antibodies or environmental toxins). The material will also enable analyses of DNA, serum and cerebrospinal fluid related to the progression of the disease, prognosis and treatment effect of medications.

Conditions for access to and use of registered information and samples

Only a small number of authorised personnel and the person in charge of the registry will have access to personally identifiable information. They are all subject to a duty of confidentiality about all matters they become aware of.

Researchers who wish to access register data and biobank material must apply to the board of representatives for the Norwegian MS Registry and Biobank. In addition, all research projects must be approved by the Regional Committee for Medical and Health Research Ethics and, if relevant, by the Norwegian Data Protection Authority. In connection with research projects, only information necessary in order to conduct analyses and evaluate results will be disclosed to the persons in charge of the study. In such cases, the information will identified only with a register-specific number, and your identity will not be available. Results from research projects will be presented in such a way that it is not possible to identify individuals.

It may become relevant to have material analysed at laboratories abroad, both within the EU/EEA, but also in the USA and other countries that may have less strict data protection legislation. Helse Bergen health trust, as the data controller, has its own procedures in place to ensure that data protection considerations are safeguarded, even in case of information being disclosed to countries outside the EU/EEA. In such cases, you will be asked to consent to register information and/or samples being exchanged with researchers engaged in such projects. Disclosure of data or samples will only take place by application from projects that meet the relevant formal and scientific requirements.

For special research projects, it may be relevant to align data from the Norwegian MS Registry and Biobank with other information from patient records and from other public registers such as the National Population Register, the Medical Birth Registry, the Cause of Death Registry, the Norwegian

Immunisation Registry (SYSVAK), the Cancer Registry of Norway, the Norwegian Patient Registry, the Norwegian Prescription Database, the National Service Administration and Statistics Norway's registers, for example on education, labour force participation and welfare benefits. Such alignment of data requires the advance approval of the required bodies, such as the Regional Committee for Medical and Health Research Ethics, the Norwegian Data Protection Authority, the Directorate of Health or the Norwegian Labour and Welfare Administration (NAV). All information will be processed with respect for data protection and privacy and in compliance with the applicable laws and regulations.

Registration and samples for the Norwegian MS Registry and Biobank

Your doctor/neurologist will first fill in a registration form with information obtained from you and your patient record before the Norwegian MS Registry and Biobank send blood sample vials. We will also contact your hospital laboratory to request access to cerebrospinal fluid already collected as part of the investigation of your illness.

Storage, right of access and rectification and erasure of data

Registered information and samples collected from you will be stored in the Norwegian MS Registry and pertaining biobank. The information registered will be personally identifiable. This is to ensure that the Registry can be updated with new information. The data are stored in accordance with the applicable legislation. The information is stored indefinitely in accordance with the applicable licence from the Norwegian Data Protection Authority. All information contained in the Norwegian MS Registry and Biobank will be treated as strictly confidential.

You are entitled to access the information registered about you and have registered information that you can document to be incorrect or incomplete corrected or completed. You can demand to be erased from the Registry. You can demand that material you have contributed to the biobank be destroyed or handed over to you. However, you cannot demand that material and data that have been used and perhaps even published in scientific works be destroyed/erased.

By signing the enclosed consent form, you confirm that you have received a copy of this information letter and that you consent to being registered in the Norwegian MS Registry and Biobank.

Contact address

Enquiries can addressed to the Norwegian MS Register and Biobank, Department of Neurology, Haukeland University Hospital, NO-5021 Bergen. Phone: (+47) 55 97 55 03,
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