HELSE BERGEN
Haukeland universitetssjukehus

Declaration of consent

Request for participation in the Registry and Research biobank for organ-specific autoimmune diseases

The registry for organ-specific autoimmune diseases (ROAS) was founded in 1996 at Haukeland University Hospital and University of Bergen and is a national medical quality registry approved by the Norwegian Data Protection Authority (Datatilsynet), and the Norwegian Ministry of Health and Care Services, and owned and financed by the Western Norway Regional Health Authority (Helse Vest). ROAS is first and foremost a registry for patients with primary adrenal insufficiency and polyendocrine failure, but it also includes other patient groups. Bergen Hospital Trust (Helse Bergen) is the data controller for the registry. In the associated research biobank (FOAS) one or more blood samples are stored and in some cases other biological samples such as saliva, urine, tissue fluid and stool samples. FOAS is approved by the Western Regional Committee for Medical and Health Research Ethics (REK vest) (ref. no. 2013/1504).

The shared trait of organ-specific autoimmune diseases is that the immune system attacks one or more organs in the body which results in a loss of function. Hormone producing organs such as the thyroid gland and the insulin producing cells in the pancreas are examples of organs which are often affected by autoimmune inflammation leading to hypothyroidism and diabetes mellitus, respectively. Other rarer diseases in this group are adrenal insufficiency (Addison's disease) and ovarian insufficiency. It is not unusual for a patient to present two or more of these diseases, called polyendocrine failure.

What does participation in the registry entail for you?

Demographic data is registered in ROAS (name, address, personal identity number, year of diagnosis), clinical data (debut symptoms, diagnostic procedure, case history, familial aggregation and clinical status including quality of life), as well as treatment data (drugs and doses).

Information is collected via the treating physician and directly from patient questionnaires. In addition, information is collected from patient records. Blood samples are collected by the treating physician. Participation usually means little added time spent as information and blood sample collection for the biobank take place during regular checkups.

Your participation also means that you consent to having information from any questionnaires you have answered handed out to the health institution (hospital/general practitioner's office/physician) that is treating you. Some will use this information for quality assurance of the treatment you are receiving, in your future check-ups, or for research purposes. Health institutions that ask to receive data from questionnaires cannot use the data for quality assurance or research purposes without concession from the Norwegian Data Protection Authority, recommendation from a Data Protection Officer or approval from the regional ethics committee.

Possible advantages and disadvantages of participation in the registry

Your participation will promote research and help us ensure state-of-the-art quality of the treatment you are receiving.

The purpose of ROAS is to:

- Understand why organ-specific autoimmune diseases occur
- Find better diagnostic methods
- Establish new and improved treatment, ideally treatment that may prevent the development of these diseases
- Improve patient follow-up
- Spread knowledge about these diseases to patients, dependents and society as a whole

The information and samples for the biobank will be used to study everything from occurrence of autoimmune diseases and quality of life, to analysis of the immune system, hormones, and hereditary factors, particularly with regards to the endocrine and immune systems. Our goal is to gain increased understanding of these diseases.

Participation involves few disadvantages, since information and blood samples can be collected during outpatient visits. Your participation causes no further disadvantages for you other than that you may be contacted for additional information.

Study of hereditary factors

Modern studies of hereditary factors include the study of large parts of human DNA. All humans have rare variants in their DNA. Very rarely we may unintentionally find known mutation that with certainty will cause preventable and/or treatable diseases. Intervention in these cases may improve health and is therefore considered good practice. Abnormal genes for breast cancer is one example. However, it may be a psychological burden to know of potentially harmful gene variants. You are therefore completely free to choose whether or not you would like to be informed of such a finding should we find one (see the declaration of consent form). In very rare cases gene findings will be of such a serious character that we have a duty to inform you in order to start necessary medical treatment. This will only happen after careful assessment and after consulting the regional ethics committee and an expert group. Gene factors will not be studied in children under the age of 16. If you would like more information about the study of genetic factors, you can contact us (see contact information below).

Voluntary participation and possibility to withdraw consent.

Participation is voluntary. If you agree to participate, you sign the declaration of consent on the last page of this document. Refusal to consent will not have any impact on your course of treatment.

Even if you agree to participate, you may later withdraw your consent without it impacting your treatment. If you later wish to withdraw you may contact ROAS by sending an e-mail to addison@helse-bergen.no or call 55 97 30 77.

What happens to the information collected about you?

The information that is registered about you is stored electronically in a database approved by the Norwegian Data Protection Authority. The database is secured from unauthorized access. The information will only be handled by authorized personnel at the hospital, and the results of studies will be anonymous.

Information will be stored until the end of year 2030, depending on the continued approval from the Norwegian Data Protection Authority. All data will be deleted when the approval ceases.

Yearly national reports will be compiled from the registry. Results will also be published at medical meetings and in national and international medical journals. Results based on analyses from the registry will not identify subjects.

By participating, you also consent to having information about you handed over to other researchers in Norway and abroad. The code that connects you to your personally identifiable information will not be handed over. These countries may have laws that do not meet European privacy law. Countries in cooperation with ROAS as of now are Sweden, England, Germany, Estonia, Finland, Israel and the USA.

Connection with other registries

For research purposes it may be relevant to compare information from the registry with information from hospitals patient records and from the following public registries: Norwegian Patient Registry, Cause of Death Registry, Medical Birth Registry, Prescription Database Registry, and other similar registries. Connections to the Norwegian Patient Registry will be performed regularly to estimate the coverage and validity of ROAS.

All such connections require consent and/or advance approval from the public instances that the law requires, such as the Regional Committee for Medical and Health Research Ethics, the Norwegian Data Protection Authority and the Ministry of Health and Care Services.

Your right of access to and removal of information

You may at any time be granted access to the information that is registered about you. You also have the right to have any uncorrect information corrected. You may at any point demand to have any and all collected biological samples and information about you deleted from the registry, without giving a reason. Removal of data and biobank materials will not mean deletion from anonymized research files that have already been used in research.

Privacy

All information will be treated with respect to privacy, and in accordance with laws and bylaws. Furthermore, all information will be treated confidentially, and everyone working with the registry has an obligation to observe confidentiality with regards to any information they become privy to.

Research projects

All research projects must be approved by the Regional Committee for Medical and Health Research Ethics and any other public bodies that the law demands. When a project is approved, you may find information about it at www.haukeland.no/roas.

HELSE BERGEN
Haukeland universitetssjukehus

If you have any questions regarding the research activities, please contact:

Eystein Husebye, MD, PhD
Professor, consultant

Phone 55973078/5000
eystein.sverre.husebye@helse-bergen.no

Marianne Grytaas, MD
Consultant

Phone 55978432/5000
Marianne.grytaas@helse-bergen.no

HELSE BERGEN
Haukeland universitetssjukehus

Declaration of Consent
- Adults over the age of 16

Registry

Registry and Research biobank for organ-specific autoimmune diseases (ROAS and FOAS)

Name of registry leader:	Clinic/department
Eystein S. Husebye	Department of Medicine, Haukeland University Hospital

I hereby consent to the storage of information and samples about me in the Registry and Research biobank for organ-specific autoimmune diseases, for quality assurance purposes and future research within this area of study.

[ ] I would like to be informed of any accidental findings of gene variants which give high risk of a hereditary disease and for which there exists effective treatment and/or prevention.

Name in block letters	Norwegian identity number (11 digits)

Date	Signature

To be filled out by a representative of the research area

I confirm that I have given information about the Registry and Research biobank for organ-specific autoimmune diseases.

Name in block letters

Date	Signature

HELSE BERGEN
Haukeland universitetssjukehus

Declaration of consent
- Children under the age of 16

Registry

Registry and Research biobank for organ-specific autoimmune diseases (ROAS and FOAS)

Name of registry leader:	Clinic/department
Eystein S. Husebye	Department of Medicine, Haukeland University Hospital

I hereby consent on behalf of the child to the storage of information and samples about the child in the Registry and Research biobank for organ-specific autoimmune diseases, for quality assurance purposes and future research within this area of study.

Name of the child in block letters	Childs Norwegian identity number (11 digits)

Date	Guardian's signature	Role (mother, father, guardian)

To be filled out by a representative of the research area

I confirm that I have given information about the Registry and Research biobank for organ-specific autoimmune diseases.

Name in block letters

Date	Signature

Comments: