HELSE BERGEN
Haukeland universitetssjukehus

Declaration of consent

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

The registry for organ-specific autoimmune diseases (ROAS) was founded in 1996 at Haukeland University Hospital and the University of Bergen and is a National medical quality registry approved by 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. The research biobank 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 so that relatively slow metabolism (hypothyroidism) and diabetes mellitus occurs. Other rarer diseases in this group are adrenal insufficiency (Addison's disease) and ovarian failure. It is not unusual for a patient to eventually present with multiple of these diseases (polyendocrine failure).

What does participation in the registry entail for you?

Demographic data is registered in ROAS (e.g. 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 (compound types and doses). The registry will also store limited genetic data, such as variations/mutations of potentially disease causing genes.

In the associated research biobank one or more blood samples are stored and in some cases other biological samples such as saliva, urine, tissue fluid and stool sample as well.

Information is collected via the treating physician during checkups and diagnosis, and directly from patient forms. Information is additionally collected from patient journals. Participation usually means little added time spent as information and blood sample collection happens during checkups.

Possible advantages and disadvantages of participation in the registry

Your participation can help us assure the quality of the treatment you have or 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 life quality, to analysis of hereditary factors, the immune system, and hormones.

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

Studies of hereditary factors

State of the art enquiries into hereditory factors entail investigating large portions of the genome. In rare occasions, we may disover a genetic disposition with a high risk of causing a condition that could be either prevented or managed. Intervention will in those case improve your health and be considered good medicine. Genetic variants causing breast cancer is an example of this. On the other hand, receiving such information can be a psychological burden. You are free to decide yourself if you are interested to be informed in such cases (see the consent page). In extremely rare cases, the genetic variant can be so serious that we have a duty to contact you in order to provide the necessary medical treatment. This will only happen after consultation with the regional ethics committee. Investigations of hereditary material will not be performed on children below the age of 16, unless specific consent is provided. If you want further information regarding genetic studies, please contact the registry (contact information is provided 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 impact on your treatment. If you later wish to withdraw you may contact ROAS by sending an e-mail to addison@helse-bergen.no or call +47 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 etc. will be anonymous.

Information and biobank samples will be stored as long as necessary to achieve the purpose of the register.

Yearly national reports will be compiled from the registry. Results will also be published continuously at specialists 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 and/or biobank samples handed over to other researchers in Norway and abroad. The code that connects you to your personally identifiable information will not be handed over.

This may be countries with laws that don't meet European privacy law.

Countries currently in cooperation with ROAS:

Sweden, England, Germany, Estonia, Finland, Israel, USA.

Connection with other registries

For research purposes it may be relevant to compile (connect) information from the registry with other information from the hospitals patient journal and from the following other 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 done regularly to measure 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 mistakes corrected in the information we have registered about you. 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 are already used in research.

HELSE BERGEN
Haukeland universitetssjukehus

Privacy

All information will be treated with respect to privacy, and in accordance with laws and bylaws. Further, 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.

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

Eystein Husebye

Professor, Attending dr med

Ph. 55973078/5000

eyhu@helse-bergen.no

Kristian Løvås

Attending, professor, dr med

Ph. 55977996/5000

kral@helse-bergen.no

HELSE BERGEN
Haukeland universitetssjukehus

Declaration of Consent
- Adults over the age of 16

Registry

Registry for organ-specific autoimmune diseases (ROAS)

Name of registry leader:	Clinic/department
Eystein S. Husebye	Medical department, 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.

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

Comments:

HELSE BERGEN
Haukeland universitetssjukehus

Declaration of consent
- Children between 12 and 16 years old

Registry
Registry for organ-specific autoimmune diseases (ROAS)

Name of registry leader:	Clinic/department
Eystein S. Husebye	Medical department, 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	Guardians 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: