HELSE BERGEN
Haukeland universitetssjukehus

Declaration of consent ROAS

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, family members and healthy volunteers. Bergen Hospital Trust (Helse Bergen) is the data controller for the registry. The research biobank FOAS holds mostly blood and serum, but also saliva, urine, feces and tissue 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. Hypothyroidism and diabetes type 1 are the most common organ-specific diseases caused by failure of hormone production, while adrenal insufficiency (also known as Addison's disease) and ovarian failure are rarer. 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?

Information is collected via the treating physician during diagnosis and checkups and diagnosis, and directly from questionnaires. Information can also be collected from your patient journal. Participation in the registry does not require extra doctoral visits, information and blood sample collection happens during routine checkups.

Participating in the registry also means that you consent to information from questionnaires you fill out, can be shared your local health institution (hospital, doctor) for use in quality control, for use in treatment or for research purposes. Approvals from the regional ethic committees or data protection act is required for use of such information.

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.

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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 registry information and samples for the biobank will be used for a large spectrum of analyses, from occurrence of autoimmune diseases and life quality, to analysis of hereditary factors, the immune system, and hormones. The overall aim is to improve our understanding of the 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.

Studies of hereditary factors

Using modern methods of detecting hereditary disease factors, we will investigate large portions of the genome. In rare occasions, we may therefore discover that you have a genetic disposition with a high risk of causing a condition that could be either prevented or managed. In some of these cases intervention could improve your health and be considered good medicine. On the other hand, receiving such information can be a psychological burden.

You have to make the decision whether you want 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).

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. Publishing results is a necessary part of the research process. Data in published research will be de-identified to preserve the privacy of individual participants, but we have a duty to inform you that we cannot rule out that there is a chance of individuals being identified.

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 do not meet European privacy law.

Countries currently in cooperation with ROAS:

Sweden, Great Britain, 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

Participation in the project is voluntary. If you would like to participate, please sign the consent form at the end of this document. You can withdraw your consent at any time without giving a reason. There will be no negative consequences for you or your treatment if you do not want to participate or if you choose to withdraw at a later stage.

You have the right to access the information that is registered about you and to have any errors in this information corrected. You also have the right to information about the data security measures that apply to the processing of the data. You can lodge a complaint about the processing of your data to the Norwegian Data Protection Authority and the institution's Data Protection Officer.

If you withdraw your consent, your health data and biological material will not be used in any further research. You can request access to the data held on you, and this will be provided within 30 days. You can also apply for your data in the project to be deleted and for your biological material to be destroyed.

The right to have your data and material destroyed, deleted or returned does not apply if the material or that there is a chance of that there is a chance of data are anonymised or

have already been published. Access may also be restricted if the data have been included in analyses already performed, or if the material has been processed and is part of another biological product.

Privacy and contact information

Our data processing is based on the General Data Protection Regulation article 6, 1e and article 2h, i and j. Personal information will only be used as described under the aim of the registry and will be stores as long as required to reach the objective of the registry.

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.

If you have questions about the project or want to withdraw your participation, you can contact Eystein Huseby at addison@helse-bergen.no or +57 55 97 3077
If you have questions about data protection in the project, you can contact the Data Protection Officer at the institution: personvernombudet@helse-bergen.no

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, https://www.facebook.com/ROASBergen and https://www.uib.no/fg/endokrin

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

Eystein Husebye

Professor, Attending dr med

Ph. 55973078/5000

eyhu@helse-bergen.no

Registry administration

Ph. 55973077

addison@helse-bergen.no

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Joining the registry if you are under 12 years old.

Why are you asked to join?

You are receiving this letter because you have a disease where you are missing one or more hormones in the body.

Doctors and scientists wish to learn more about your disease, so we can find the best treatment for you and others with the same disease. To do that we want to collect information about you and others in something that is called a patient registry.

Our registry is named ROAS. We collect information on your age, when you became sick, what disease you have and what medicine you use. We will also use your blood samples to try to discover the reason for the disease and how to treat it.

What happens to you in the registry

Your parents will decide if they want you to be a part of our registry. If they say yes, your doctor will provide us with the necessary information. We also want a sample of your blood. This sample will be collected when you are already are giving samples at the doctor, so you won't need an extra needle stab. Every time you see a doctor, he will send new information about you to the registry.

What will happen if you do not join the registry

Participation is voluntary, and it is your parents that choose if you participate. If you do not wish to join, that is completely okay and will not change your treatment.

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Joining the registry if you are 12-16 years old.

The registry for autoimmune organ-specific diseases (ROAS) is a national quality patient registry for children and adults with adrenal insufficiency and other conditions where you produce less hormones. In the registry, we collect information and blood samples from persons with these conditions. We only collect information if you have consented to join.

The main purpose of ROAS is to learn more about how these hormone-deficiency diseases arise and to improve follow up and treatment of patients.

We recommend that you discuss with your parents if you should join the registry. It is your parents that has the final say and sign the consent form, but you have a right to voice your opinion. If you choose to participate in ROAS, we will register information on you, including which diseases you have, when you were diagnosed, your treatment plan and any relevant information about similar diseases among your family members. We also wish to receive blood samples from you for research.

Benefits and drawbacks

Samples and information will be collected and transferred to the registry when you are at the doctor for your regular check-ups, so you won't have to do extra visits. The blood samples will be taken together with your other samples.

What happens to information about you and your blood samples

Your information will be stored electronically in a secure database belonging to Helse Bergen. The blood samples will be stored in a local biobank freezer. Only persons associated with the registry will have access to the registry, the information and your samples. Your information and samples can be provided in an anonymized form to research projects if they have all the required permissions.

Participation

Participation in ROAS is voluntary. You may at any time withdraw from the registry, and this will not affect your treatment. When you turn 16, you can make the decision to withdraw yourself, and we will send you a letter describing your rights. Please contact us if you have any questions about the registry at 55973077 or addison@helse-bergen.no.

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Registrationform

Register for organspesifikke autoimmune sykdommer

Name: ID-number:

Address: Postcode:

Symptoms	YES	Year of diagnosis	**Symptoms**	YES	Year of diagnosis
Adrenal insufficiency (Addison's disease)			Vitiligo		
Hypothyroidism			Alopecia		
Hyperthyroidism			Chronic candidais		
Type 1 diabetes			Enamel injury		
Pernicious anemia			Corneal inflammation		
Hypoparathyroidism			Liver disease (specify)		
Early menopause or testicular failure			Kidney disease (specify below)		
Celiac disease			Nerval damages (specify below)		
Malabsorption			Other diseases (specify below)		

The form can be sent together with the consentform and eventual blood samples to:
Register for organspesifikke endokrine sykdommer, Medisinsk avdeling, Haukeland Sykehus, 5021 Bergen.

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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:

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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: