



## Request for participation in a research project

### Background and purpose

This is to invite you as a healthy family member to participate in the research study *Epidemiological, Genetic and Clinical studies of Monogenic Diabetes*. There are two main types of diabetes: type 1 (most commonly affects children and adolescents) and type 2 (occurs primarily in adults and especially in excess). A third and more rare type is monogenic diabetes including MODY (Maturity-Onset Diabetes of the Young) and neonatal diabetes. In MODY, diabetes usually occurs before 25 years of age. Inheritance is special in that the disease breaks out in every generation. Neonatal diabetes occurs before 6 months of age and there are both spontaneous and inherited forms. Important research goals are to find out how widespread monogenic diabetes is, the genetic changes that are present, and how treatment can be improved. The project has a scientific and a practical side. Scientifically, the research will shed new light on the inheritance of diabetes and increase the knowledge of the causes. The practical value lies in the genetic typing is important for patient follow-up because some forms of diabetes can be treated without insulin and there are good long term prospects.

### How is the study performed?

We record the age, gender, place of residence and information from medical records. We also want to investigate people who do not have diabetes to compare with those in your family that have diabetes. Participation involves a blood sample taken from the arm. It may be that we will contact you with questions to participate in additional projects to find out more about issues related to the disease. It may also be that collaborative international laboratories involved in any analysis. De-identified biological materials will in that case be sent to foreign countries.

### Possible advantages and disadvantages of participating in the study

Possible benefits are that we can find out why some in your family have diabetes and how many people have this. It may be that we will find that they have a special form of diabetes and that it has implications for treatment and prognosis. The possible downside is that the study involves the storage of data and blood samples in the repository, additional examinations and blood tests. There are no special risks of the investigations.

### What happens to the samples and information?

The information and samples as described in the purpose of the study. The information is stored on a separate computer at Haukeland University Hospital. Names and personal identity can only be connected with information about you through a code that only authorized personnel have access to. The CEO is responsible for the computing. It may be appropriate to link to the National Register, the Norwegian Medical Birth, Cause of Death Register and the Norwegian Patient Register. Blood samples are stored in a biobank research. Prof. Pål R. Njølstad is responsible for the biobank. Deletion of information and removal of blood samples in the biobank is planned in 2016 but may be extended upon application to and approval by the Ethics Committee. It will not be impossible to identify the ID from publications.

### Voluntary participation

It is voluntary to participate. You may withdraw at any time and with no reason. Stored information will then be deleted and the samples destroyed. It will not affect the treatment of your illness. If you wish to participate, sign the consent statement. You have the right to obtain results that are important for diabetes. Contact the project manager if you have any objections or questions to the study.

Pål Rasmus Njølstad MD PhD

Helge Ræder MD PhD(sign.)

Oddmund Søvik MD PhD

NNNC Associate Investigator



Address:  
Center for Diabetes Genetics  
Department of Pediatrics  
Haukeland University Hospital  
N-5021 Bergen, Norway

Contact:  
Tel: +47-55 97 51 88  
Fax: +47-55 97 51 59  
E-mail: diabetesgenetikk@helse-bergen.no



post doc

professor emeritus

## Consent to participation in the study

### A: Patients and parents

I am willing to participate in the study *Epidemiological, genetic and clinical studies of monogenic diabetes*.

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(Name with CAPITAL LETTERS)

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(Signature by project participant, date)

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(Signature by parents, date)

For patients below 12 years, at least one of the parents needs to sign. Children between 12 and 16 years sign together with the parents. Patients older than 16 years can sign alone.

### B: Caring physician

I confirm having given information about the study

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(Signature, caring physician, date)

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NNNC Associate Investigator



Address:  
Center for Diabetes Genetics  
Department of Pediatrics  
Haukeland University Hospital  
N-5021 Bergen, Norway

Contact:  
Tel: +47-55 97 51 88  
Fax: +47-55 97 51 59  
E-mail: [diabetesgenetikk@helse-bergen.no](mailto:diabetesgenetikk@helse-bergen.no)