HELSE BERGEN HF
Haukeland University Hospital
CENTER FOR DIABETES GENETICS
DEPARTMENT OF PEDIATRICS
HAUKELAND UNIV. HOSPITAL
N-5021 BERGEN, NORWAY
TEL. (+ 47) 55 97 51 88
www.mody.no
Name and address of physician:

HELSE VEST

Birth date:_____
Name:_____
Address:_____
Country:_____
Sample date:_____

Main diagnosis:_____

Requesting diagnosis for: **MODY** ☐ **Neonatal diabetes** ☐ **Hyperinsulinism** ☐

Clinical information is important and necessary for analysis. Pleas fill in number 1-17.

Signed consent form ☐ **Available at** www.mody.no

Family data:

1. Other family members with diabetes? **Yes** ☐ **No** ☐ **Unknown** ☐
(If yes, pleas indicate which family members and type of diabetes: A drawn pedigree on the back of this page will be warmly appreciated)
2. Family members with diabetes onset before 25 years? **Yes** ☐ **No** ☐ **Unknown** ☐
3. Diabetes in at least 2 subsequent generations? **Yes** ☐ **No** ☐ **Unknown** ☐
4. Other family members with insulin treatment? **Yes** ☐ **No** ☐ **Unknown** ☐
5. Known diabetes-associated mutation in the family? **Yes** ☐ **No** ☐ **Unknown** ☐
(if yes indicate which:_____**)**

Clinical information:

6. Height: _____**cm** **Weight:** _____**kg**
7. Age at diagnosis: _____**years**
8. Fasting glucose:_____**(mmol/l)**
9. Treatment _____ Dose:_____
(Diet, tablets, insulin) _____ Dose:_____
_____ Dose:_____
10: HbA1c:_____**%(ref. range:**_____**-**_____**%)**

Complications

11. Retinopathy **Yes** ☐ **No** ☐ **Unknown** ☐
12. Coronary disease **Yes** ☐ **No** ☐ **Unknown** ☐
13. Polyneuropathy **Yes** ☐ **No** ☐ **Unknown** ☐
14. Nephropathy **Yes** ☐ **No** ☐ **Unknown** ☐
15. Kidney cysts **Yes** ☐ **No** ☐ **Unknown** ☐
16. Hypertension **Yes** ☐ **No** ☐ **Unknown** ☐

17. Other information :

_____

_____

_____

REGARDING SAMPLE AND SHIPMENT

It is important that the test tubes are shipped carefully to avoid leakage. The test tubes should be marked with date, patient name and birth date. The diagnostic form and the signed consent form must be enclosed.

Samples that might be infectious should be marked with a yellow sticker. The diagnostic form should be marked in the same way.

Material:	Sample:	Shipment
DNA	**1 microgram**	**Express mail. Room temperature is OK**
Blood for DNA analysis	**7 ml EDTA blood** **Children: 4 ml is acceptable**	**Express mail. Sample on ice. Avoid shipment over weekend.**

It is not necessary to send both DNA and blood. DNA is preferred.

It is not allowed to use the results in scientific publication without consent from the CENTER FOR DIABETES GENETICS

FOR INTERNAL USE:

Mottatt dato :_____ Sign._____ Vurdert av lege, sign._____
DNA-rensing dato :_____ Sign._____

Familienummer :_____

DNA-sekvensering

MODY-gruppen	HNF-1 alfa	Ekson:	
	GCK	Ekson:	
	Andre gener	Ekson:	
MGM	HNF-1 alfa	Hele genet	
	GCK	Hele genet	
MODY-gruppen	HNF-4 alfa	HNF-1 beta	IPF-1
(Hele genet)	INS	CEL	PRSS1
	ABCC8	KCNJ11	
Andre tester MODY-gruppen	MLPA		
	PRSS1 triplikasjonstest		
	CNV		

Andre gener/tester:

_____

_____

_____

_____

HELSE BERGEN
Haukeland University Hospital

UNIVERSITY OF BERGEN
Department of Clinical Science

Request for participation in a research project

Background and purpose

This is to invite you 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 along with excess body weight). 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. The 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 how widespread monogenic diabetes is in Norway, 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 its causes. The practical value of the project lies in the fact that genetic typing is important for patient follow-up since some forms of diabetes can be treated without insulin and there are good long-term prospects.

How is the study performed?

Age, gender, place of residence and information from medical records will be recorded. We also want to investigate people who have diabetes and any number of people in your family, both those with and without 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. Collaborative international laboratories may be involved in some analyses. 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 you have diabetes and how many people that is affected. We may find that you have a special form of diabetes and that this has implications for treatment and prognosis. The possible downside is that the study involves the storage of data and blood samples, and additional examinations and blood tests may be requested. There are no special risks associated with the investigations.

What happens to the samples and information?

The information and samples are used 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 of Helse Bergen is the data controller. It may be relevant to link to the National Registry, the Medical Birth Registry, the Cause of Death Registry and the Norwegian Patient Registry. Blood samples are stored in a research biobank. Helse-Bergen, Haukeland University Hospital, is responsible for the biobank. Deletion of information and removal of blood samples from the biobank is planned in 2022, but may be extended upon application to and approval by the Ethics Committee. It will not be possible to identify you from the study results if published.

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. This will not affect the treatment of your illness. If you wish to participate, please sign the consent statement. You have the right to obtain results that are important for your diabetes. Contact the project manager if you have any objections or questions regarding the study.

Pål Rasmus Njølstad MD PhD
Professor, leader

Jørn V. Sagen MD PhD
Professor

Janne Molnes, PhD
Senior engineer

K.G. Jebsen Center for Diabetes Research
University of Bergen
Children and Youth Hospital, 6th floor, Block 2
Haukeland University Hospital
N-5021 Bergen
NORWAY
pal.njolstad@uib
Tel: +47-55 97 08 70

European Research Council
STIFTELSEN KGJ

Consent to participate in the study

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

(Name with CAPITAL LETTERS)

(Signature by project participant, date)

(Signature by parents, date)

For patients below 16 years, at least one of the parents needs to sign. Patients older than 16 years can sign alone.

B: Caring physician
I confirm to have given information about the study

(Signature, caring physician, date)

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Tel: +47-55 97 08 70

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