

Consent form for the registration of data in the Norwegian Diabetes Register for Adults

The aims of the register

The Norwegian Diabetes Register for Adults is a National Quality Register. The primary aim of the Register is to improve the quality of the treatment of people with diabetes. The register will also provide data for research on diabetes and diabetes related conditions. The Register is approved by the Data Inspectorate. Recording of data about your diabetes is voluntary and requires written informed consent. This means that you have to sign the consent form before we record information about your diabetes.

The Register will record the following information about you:

- General information: Name, personal number, address, gender and name of your General Practitioner. The National Registry will be used to check information.
- Health information: Type of diabetes, year of diagnosis, membership in Norwegian Diabetes Association, results of annual diabetes check-up including retina examination and/or referral to diabetologist, complications, height, weight, results of laboratory examinations, prescribed medicines for diabetes and heart disease, together with diabetes education.
- Patient reported outcome measures: Information about quality of life and different aspects or challenges associated with living with diabetes.

It is also possible that we may ask you to provide an extra blood or urine sample, for example when you consult your doctor. These samples will be stored frozen in a bio-bank and only used for diabetes related research.

Your diabetes doctor will transfer information regularly (usually annually) from your case notes to the Norwegian Diabetes Register for Adults, or you may supply the information to the Register yourself. Bergen Health Trust, Haukeland University Hospital, owns the register and is responsible for ensuring that the health information in the register is processed according to regulations that apply to the processing of personal data and upkeep of the bio-bank. Noklus¹ are responsible for the development and the day-to-day running of the Register. Noklus is located at Haraldsplass Diaconal Hospital in Bergen. Transfer of information about your diabetes uses secure data technology, and is protected against unauthorized access. For research purposes, or to check that information about you is correct and complete, it may be necessary to obtain diabetes related information from other national registers. A notification will appear on our home site each time such a linkage is performed. The Children's Diabetes Register, The Prescription Register, The Kidney Register, the Cardiovascular Register, the Medical Birth Registry, The Cancer Registry, The Registry of Deaths, The Education Registry, The Sick Leave Registry and the Norwegian Patient Register (includes information about all patients that are treated at hospitals or by practicing specialists) are examples of registers where data linkage might be necessary.

Information is stored permanently electronically. The administration of the information is approved by the Data Directorate according to Personal Information Law §33. Information is stored securely and all staff who work with information from the Register are bound by strict confidentiality laws.

Right to read, alter or delete information

You are entitled to read the information the Register has about you. In addition you can, without giving any reason, demand to have the information concerning you deleted from the Register, and the blood and urine samples destroyed. This right is in accordance with paragraph 18, 27, and 29 in the Personal Information Law and §14 in The Bio-bank Law. Your Doctor is aware of this, and it will not affect your relationship to your Doctor if you decide not to allow information about you to be recorded, or withdraw consent at a later stage.

Information from the Register will only be disclosed to researchers in anonymous form. This means that your identity will be concealed and your name, and other identifiable features will only be stored at the Norwegian Diabetes Register for Adults. More information about the Norwegian Diabetes Register for Adults can be obtained by contacting Noklus, tel 55 97 95 00.

¹ Noklus Noklus is an abbreviation for Norsk kvalitetsforbedring av laboratorievirksomhet utenfor sykehus

WRITTEN CONSENT

I have read the information form about Norwegian Diabetes Register for Adults and understand that a Diabetes Register for Adults has been established at Noklus in Bergen. Bergen Health Trust, Haukeland University Hospital, owns the register and is responsible for ensuring that the health information in the register is processed according to regulations that apply to the processing of personal data and upkeep of the bio-bank.

After reading the information form I understand the aims of the Register, which information will be recorded, where the information will be found, how the information will be collected, how information may be disclosed and my rights with respect to reading, altering or deleting information in the Register

I understand that information about my diabetes will be transferred to the Diabetes Register and that I can be asked to donate a blood and urine sample to a Research Bio-bank, that will be part of the Register. The samples in the Bio-bank will only be used in diabetes related research.

I hereby consent to information about my diabetes and results from blood tests and urine tests being included in the Norwegian Diabetes Register for Adults, and that the Register can contact me in connection with diabetes related research.

Name.....
(Use Capital Letters)

Personalnumber.....
(11 digits)

Place..... Date.....

.....
Signature

The consent form can be delivered to your Doctor or posted to
Norsk diabetesregister for voksne
Noklus
Boks 6165
5892 Bergen

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