Information on kidney failure treatment in Norway
Norwegian Renal Registry

Background and purpose

Following the initiative of Norwegian nephrologists, a registry has been established for information on diagnosis and treatment of chronic kidney disease. In addition, patients in need of beta-cell replacement therapy (insulin producing cells for patients with diabetes) are also included in the registry as most of these are also kidney transplanted. The registry is operated at Oslo University Hospital HF in close collaboration with the country's pathologists, nephrologists and the *Norwegian Kidney Medicine Association*.

Why is information on kidney failure treatment and diagnostics (e.g. kidney biopsies) collected?

- To have an overview of how many patients are being treated and how the need is developing, in order to have access to the necessary treatment capacity in the right places.
- Treatment is complicated and many conditions affect treatment outcomes for patients. By gathering important medical information about the patients being treated, and about different aspects of the treatment they are receiving, one can both gain new medical knowledge and find out how the treatment of each individual patient can be improved.
- By gathering information showing the quality of the treatment given, the registry can help each treatment center to ensure that it offers adequate patient care.

What happens to the information about you?

The information recorded about you will only be used as described in this information. Your information cannot be included in any research until the project is approved by the Data Protection Officer (*Personvernombudet*) at Oslo University Hospital HF and the Regional Committee for Medical and Health Research Ethics. All information will be processed *de-identified*, that is, without name and social security number (*fødselsnummer*) or other directly recognizable information. A code links you to your information through a name list. Only a limited number of people at the registry can identify you.
In research and quality studies, there may be a need for linking your data to regulated registries (for example, the National Population Register, the Cancer Registry, the Medical Birth Registry, the Cause of Death Registry, the Patient Registry or the Prescription Database). It will not be possible to identify you in the results of when such studies are published.

Voluntary participation

It is voluntary to give consent to the registration. You can withdraw your consent at any time and without giving any reason. This will not have any consequences for your further treatment. If you agree to participate, sign the Declaration of Consent on the last page. If you now agree to participate, you can later withdraw your consent without affecting your other treatment.
If you later wish to withdraw or have any questions regarding the registry please contact Professor Anders Åsberg (aaasbe@ous-hf) or Dr. Anna Varberg Reisæter, Department of Nephrology, Department for Transplantation Medicine, OUS (switchboard: 23 07 00 00 or http://www.kvalitetsregistre.no/resultater/nyre/). Questions about data privacy in the registry are handled by the data protection officer at Oslo University Hospital: personvern@ous-hf.no.

Further information about the registration can be found in Chapter *A* - *a detailed explanation of what the registration entails.*
For more information on privacy, see Chapter B- *Privacy*
Declaration of consent follows Chapter B

Chapter A - detailed explanation of what registration means

Who is asked to register in the "Norwegian Renal Registry"?
People in Norway who have started diagnostic procedures or treatment due to severe kidney disease and people who are going to undergo beta-cell replacement therapy.

What does it mean for you to participate in the registry?
The registration and submission of information to the registry is usually done by the nephrologist who follow-up each individual patient. Responsible for reporting practice at the individual kidney section is the section superior.

Is there any risk in registering?
It is emphasized that consent to registration in the Norwegian Renal Registry does not entail any obligations for the individual. The registry is subject to strict privacy and information security requirements so that information is not misinterpreted or misused.

What medical information is recorded?
At the start of diagnostic procedures (for example, kidney biopsy) or treatment, what type of kidney disease is being diagnosed and whether there are other important complicating diseases, such as diabetes, cancer, cardiovascular disease and the like. If a kidney biopsy is taken, information on the biopsy (for example degree of kidney tissue loss) is recorded. The doctor provides information on the treatment options (preventive treatment, hemodialysis, peritoneal dialysis, transplantation) and some important medications used. Later it is recorded whether the patients change treatment. The data collected is primarily based on information from your patient record, including blood and urine test results, but relevant diagnoses and the like can also be collected from various registers, such as the Norwegian Patient Registry and the National Population Register.

In such a registry it is essential to avoid double registration and that all follow-up is connected to the right person. Therefore, the registry is based on social security number and uses a computer program that checks that the same person is not registered multiple times. By means of social security numbers and the National Population Register, one can ensure that the registry is kept up to date if someone dies or moves to another treatment center. The use of social security numbers may allow (after special application to health authorities) the registry to cooperate with other registries, for example to determine if any conditions in the treatment affect the risk of other illness. Names are used only to facilitate contact between the registry and treating nephrologists.

About each new-year, information about the treatment and specific complications related to the treatment during the previous year is collected. For patients who have undergone kidney biopsy, information about the treatment itself and the results of urine and blood tests relevant to the course of kidney disease is collected. For dialysis patients, information about the treatment itself and the result of urine and blood tests that say something about dialysis efficiency is collected. Information on organ function and immunosuppressive drugs is collected for kidney transplant and patients with beta-cell replacement transplants. For all, results from various urine and blood tests and examinations, such as blood percentage, blood pressure and cholesterol and treatment for this, in addition weight and height, smoking and a simple rehabilitation status s collected.

Chapter B - Privacy

Privacy
Information recorded about you will apply to conditions that we believe may be important for the development and progression of severe kidney disease and after beta-cell replacement therapy. We will primarily use information from your medical record at the medical department that treats you and from the Norwegian Patient Registry and the National Population Register. Occasionally it will be necessary to obtain supplementary information of a similar type from the medical records of a general practitioner or other health institution.

In some projects, it will be necessary to link quality and research data to other registers. Such linking will only occur after prior approval by the Data Protection Officer (*Personvernombudet*) at Oslo University Hospital and the Regional Committee for Medical and Health Research Ethics. Information from relevant registers includes: Possible cancer incidence (Cancer Registry), cause of death (Death Cause Registry), medical conditions around birth (Medical Birth registry), drug treatment (Prescription Database). All data is stored in accordance with current procedures approved by the Data Protection Officer.

All information will be treated confidentially. No other than the head of the registry and his deputy has access to all information in the registry. The nephrologists at a treatment center can obtain a copy of all information about patients from their center.

The registry will keep your information indefinitely. The register has a legal basis in the general data protection regulation article 6 no. 1 letter e) and article 9 no. 2 letter j). The conditions for legally retaining the information will be continuously reviewed.

Oslo University Hospital HF at the CEO is responsible for data processing.

Disclosure of information to others
If you consent to registration in the Norwegian Renal Registry, this also means that necessary identifiable information, if applicable, is registered on the joint Nordic waiting list system for organ transplantation (Scandiatransplant), as well as information on transplantation and any loss of graft, with loss of cause. Only authorized personnel have access to this registry, which is necessary for proper organ allocation.

De-identified information, where the name and social security number is replaced by a code, will also be transferred to a joint European Treatment Registry (ERA-EDTA Registry) in Amsterdam, as well as the Nordic database of peritoneal dialysis planned to be established in Denmark. Pancreatic transplants will be reported to the International Pancreatic Transplantation Registry (IPTR) in Minneapolis, USA.

Research often takes place through collaboration between different institutions and often takes place across national borders. It may therefore be appropriate to send de-identified information to partners at other institutions and industrial partners both in Norway and abroad. This may be countries' not have the same legal requirements for privacy, but privacy will be safeguarded in agreement basis (EU standard contract or Safe Harbor).

Right of access and deletion of information about you and deletion of samples
If you agree to participate, you have the right to have access to the information that is registered about you. You also have the right to correct any errors in the information we have recorded. If

you withdraw from the registry you may be required to delete the collected information, unless the information has already been included in analyzes or used in scientific publications.

Information on the outcome of the studies

Participants are entitled to receive information on the results of studies being conducted. Each year the registry publishes an overview of which analyzes have been performed on data in the registry at www.nephro.no and corresponding data are presented in LNT news. An annual report for the registry will also be published on www.nephro.no. Study results are available as publications in Norwegian and international scientific journals. Publications will never contain information that can identify you or any other individual patient.

Consent for registration in the Norwegian Renal Registry - adults over 16 years

I agree that samples and information can be collected and registered in the Norwegian Renal Registry and used for quality assurance and research in this area.

Patient name:_____

Norwegian national identification number (11 digits): _____

Date (Signed by project participant)

Deputy consent when justified, either in addition to the person himself or instead

(Signed by relatives, date)

I confirm having provided information about the registration

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Date (Signed by doctor) medical stamp

Form is sent in connection with the patient:
[ ]: takes biopsy, [ ]: gets into CKD5, [ ]: starts RRT, [ ] is pancreatic/islet cell transplanted

Signed consent declaration is sent to the Norwegian Renal Registry along with the first submission of a message to the registry. Copies of consent must also be stored locally.

Norsk Nyreregister
Nyreseksjonen, ATX
Oslo Universitetssykehus HF, Rikshospitalet
Postboks 4950 Nydalen
0424 Oslo

Consent to register in the Norwegian Renal Registry - children under 16 years

I have read the information on behalf of the child "*Information about kidney failure treatment in Norway – the Norwegian Renal Registry*", and is made aware of the purpose of the registry, what personal data is to be registered, where the information is obtained from, how the information is to be provided, and what rights my child has with regard to access, change and deletion of information in the registry.

I am aware that information is retrieved from my child's journal, which will be part of the registry. Collected samples and information will only be used in quality assurance of patient care and in research that appears in the information document**.**

I hereby agree on behalf of the child that samples and information can be collected and registered in the Norwegian Renal Registry and used for quality assurance and research in this area.

Patient name:_____

Norwegian national identification number (11 digits): _____

Date (Signed by project participant)

Parental consent, either alone or in addition to the child

(Signed by parent, date)

I confirm having provided information about the registration

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Date (Signed by doctor) medical stamp

Form is sent in connection with the patient:
[ ]: takes biopsy, [ ]: gets into CKD5, [ ]: starts RRT, [ ] is pancreatic/islet cell transplanted

Signed consent declaration is sent to the Norwegian Kidney Registry along with the first submission of a message to the registry. Copies of consent must also be stored locally.

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Nyreseksjonen, ATX
Oslo Universitetssykehus HF, Rikshospitalet
Postboks 4950 Nydalen
0424 Oslo