Oslo universitetssykehus

INVITATION TO PARTICIPATE IN A QUALITY AND RESEARCH REGISTRY, AND TO PROVIDE BIOLOGICAL SAMPLES TO THE REGISTRY'S RESEARCH BIOBANK

THE NORWEGIAN REGISTRY OF PERSONS ASSESSED FOR COGNITIVE SYMPTOMS - NORCOG

This is an invitation to you as next of kin to consent on behalf of the participant to participate in the Norwegian registry of persons assessed for cognitive symptoms (NorCog). NorCog is a national quality and research registry for patients who are examined for cognitive symptoms and dementia in outpatient clinics in specialist health care services. The registry was established to improve the quality of assessment and treatment of dementia at hospital outpatient clinics in Norway.

The information collected will be used to improve the quality of our examination methods and treatment. In addition, we wish to use the information for research to improve knowledge about, among other things, disease development, use of health services and to improve our diagnostic methods.

We also ask for permission to store biological samples such as blood, saliva and spinal fluid which are taken during the assessment. The samples will be stored in a general research biobank for future research. The biological samples are stored indefinitely and will be used for future research to improve our knowledge about cognitive symptoms and dementia, risk factors, diagnostic methods and treatment. The samples will be used to study genetic material, inflammatory and stress markers, vitamins, antioxidants and other markers which may be related to memory problems.

Oslo University Hospital HF has the overall responsibility for the registry and the biobank while the Norwegian National Centre for Ageing and Health is responsible for day-to-day operation of the registry and the biobank.

WHAT DOES PARTICIPATING IN THE REGISTRY INVOLVE?

The outpatient clinic where the participant will be assessed will submit data from the examination to the NorCog registry. This will include:

1. Age, gender, education level and occupational status
2. Memory function, mental health, as well as assessments about ability to cope in daily life
3. Results of tests and examinations performed
4. Physical examination
5. Scans or images of the brain
6. Spinal fluid examination, if performed
7. Diagnosis and time of diagnosis

To enable us to follow the disease development, we wish to register information about the participant's memory and health which are registered at other outpatient clinic visits or during hospitalisation.

Furthermore, we will ask for permission to link participant's information to information that is registered about the participant in public national registries, such as the National Population Registry, the Norwegian Cause of Death Registry, the Norwegian Prescription Database, the Norwegian Patient Registry, , the Norwegian Registry for Primary Health Care (NRPC), Norwegian Cardiovascular disease Registry, National and regional health surveys and Statistics Norway. Where biological samples from the research biobank are used for research, biological data from the samples will be also linked to other data collected about the participant in the registry.

We will also ask for permission to contact you again (on behalf of the participant) to invite the participant to join in new studies not described here. All information that is registered will be stored at the Norwegian Health Network (Norsk Helsenett).

The use of data from the registry must be approved by the NorCog steering group consisting of representatives from all health regions in Norway, a user representative and a representative from the Norwegian National Centre for Ageing and Health.

WHAT ARE THE POTENTIAL ADVANTAGES AND DISADVANTAGES OF TAKING PART?

Participation in the registry does not entail any special disadvantages to the patient. The biological samples stored in the biobank is taken in connection with the routine clinical examination. We follow normal sampling procedures that do not cause any discomfort beyond what is usual with such sampling.

By participating in the registry and the biobank, participants ensure that the information obtained to provide a diagnosis and treatment, can also be used to increase the quality of the service and improve our knowledge about the assessment of cognitive symptoms. This may benefit the participant later, and it may benefit other patients. Participation in the registry, the biobank or research projects that use data from the registry will have no consequences for the participant's assessment or treatment at the outpatient clinic.

PARTICIPATION IS VOLUNTARY AND IT IS POSSIBLE TO WITHDRAW YOUR CONSENT

It is entirely voluntary to participate in the registry and to provide biological samples to the research biobank. If you consent to participate (on behalf of the participant), please sign the declaration of consent on behalf of the participant on the last page. You can withdraw your consent at any time without giving any reason, on behalf of the participant. Withdrawing consent will not have consequences for the participant's further treatment.

If you, on behalf of the participant, withdraw from the registry and / or the biobank, you can also, on behalf of the participant, request that samples and data in the registry and the biobank are removed, unless the data / sample material has already been used in analyses or used in scientific publications. If you, on behalf of the participant, later wish to withdraw or have any questions about the registry, you can contact the doctor at the outpatient clinic or one of the registry's contact persons; coordinator Marit Nåvik tel. 92246004 or project leader Geir Selbæk tel. 95883535.

WHAT HAPPENS TO THE INFORMATION AND THE STORED BIOLOGICAL SAMPLES?

The information and biological material stored will only be used as described in this information leaflet. All registered participants have the right to access and know what information is registered about them.

Participants have the right to access the information that is registered and the right to have any errors amended. You, on behalf of the participant, can request a copy of the participant's personal data. You, on behalf of the participant, also have the right to know about the security of the systems used when processing and storing information. Information about research results from biological samples will not be returned to participants. All information collected is treated confidentially, and staff who work with information from the registry have a duty of confidentiality. Data in NorCog is stored on a secure server in the Norwegian Health Network (Norsk Helsenett). Only the registry data management staff, have access to all data. It will not be possible to identify participants in the results of the studies which are published.

Research projects which use data from the registry will be approved by the Regional Ethics Committee or by the Data Protection Officer (Personvernombud). You can find information about research projects that use data from the registry on the registry website at www.norkog.no. On the website you will also find information about how to withdraw from research projects. If a research project is initiated where more data needs to be collected other than what is described here, you will be contacted again for new consent, on behalf of the participant.

The information and biological samples will be stored in the registry for as long as it is necessary to achieve the goal of the registry and the biobank.

SHARING OF DATA AND TRANSFER OF DATA OUTSIDE NORWAY

By participating in the registry, you, on behalf of the participant agree that information and biological samples may be transferred to collaborators in Norway or outside Norway as a part of a research collaboration, for analysis and publication.

Samples from the research biobank, scans or EEGs may be sent abroad for special analyses. After analysis, the samples are returned to the registry. In specific projects, it may be relevant that deidentified data to be analysed in collaboration with international research groups. These may be countries where the laws that do not comply with European privacy laws. The project leader will ensure that the participants' information is handled in a secure manner.

By contacting the Norwegian National Centre for Ageing and Health, you will get an overview of which authorities process participant's information. At www.norkog.no you will also find an overview of which authorities are responsible for the individual research projects.

FUNDING

The registry is funded from South-Eastern Norway Regional Health Authority and the National Centre for Ageing and Health.

APPROVALS

The registry has previously been granted a licence by the Norwegian Data Protection Authority. According to the new Personal Data Act, the person responsible for processing at Oslo University Hospital is Project leader/research director at Norwegian National Centre for Ageing and Health, Geir Selbæk who has an independent responsibility to ensure that the data is processed legally. This project follows the legal basis in the EU Privacy Regulation Articles 6a and 9a and processes the information about the participant based on your consent on behalf of the participant.

You, on behalf of the participant, have the right to complain about the processing of the participant's information to the Data Protection Authority.

CONTACT DETAILS

If you have questions about the registry, you can contact the registry coordinator Marit Nåvik tel. (+ 47) 92246004. Email: naam@sthf.no.

You can contact the Data Protection Officer (Personvernombud) at Oslo University Hospital by phone (+ 47) 915 02 770 or E-mail: personvern@ous-hf.no if you, on behalf of the participant, have questions about the processing of the participant's personal information in the registry.

Project leader and responsible official for the biobank: Geir Selbæk, tel. 95883535. Email: geir.selbaek@aldringoghelse.no.

Future updates to consent forms will be available on the registry's website www.norkog.no.

I CONSENT ON BEHALF OF THE PARTICIPANT TO PARTICIPATE IN THE REGISTRY AND THAT THE PARTICIPANT'S PERSONAL DATA USED AS DESCRIBED IN THIS INFORMATION LEAFLET

Name of the participant that I consent on behalf of: _____

Place and date	Next of kin's signature, on behalf of the participant	Next of kin's name in printed letters

RESEARCH BIOBANK

I agree on behalf of the participant, to give broad consent for the participant's biological samples to be stored permanently in the biobank for the Norwegian registry of persons assessed for cognitive symptoms (NorCog) and that it can be used in future research.

I, ON BEHALF OF THE PARTICIPANT, CONSENT TO THE STORAGE OF BIOLOGICAL SAMPLES

Place and date	Next of kin's signature, on behalf of the participant	Next of kin's name in printed letters

FUTURE RESEARCH PROJECTS

The third thing we ask for is permission to contact you again if we start a research project which may be relevant to the participant. If you consent to this, we kindly request you to sign here:

I, ON BEHALF OF THE PARTICIPANT, CONSENT TO BE CONTACTED AGAIN

Place and date	Next of kin's signature, on behalf of the participant	Next of kin's name in printed letters

I confirm that I have provided information about the registry and the biobank.

Place and date	Signature	Role in the registry