INVITATION TO PARTICIPATE FOR PATIENTS OVER 16 YEARS OF AGE.

NORWEGIAN REGISTER FOR PAEDIATRIC RHEUMATOLOGY (NOBAREV) AND ASSOCIATED BIOBANK

BACKGROUND AND PURPOSE

This is a request to add your information to the Norwegian Register for Paediatric Rheumatology, NOBAREV (a combined quality and research register) and to store your biological material (such as blood samples) in an associated general research biobank.

We need more knowledge in the future to provide the best treatment and follow-up of children and young people with paediatric rheumatological diseases. NOBAREV will ensure the quality of care for those who have such diseases, and increase knowledge about causal factors, incidence, health, complications, function, participation and quality of life. We will thus use the health information and biological material for paediatric rheumatology research.

The Section for Rheumatology at Oslo University Hospital (OUS) is responsible for day-to-day operation of the register. Paediatric departments and rheumatology departments from all over Norway will participate.

WHAT DOES IT MEAN TO PARTICIPATE?

We will register your name and personal identity number, the rheumatological diagnosis, other diseases you may have, how the disease developed, results of imaging examinations (such as ultrasound) and blood tests (such as inflammation blood tests and concentration of medicines in the blood) as well as medicines and any side effects of these. The information will either be registered by health personnel examining you and/or obtained from your hospital records (possibly also from other hospitals or your family doctor). You will be asked to fill in a questionnaire about your health and quality of life (this takes approx. 15-20 min). The answers to the questionnaires will be shared with the hospital where you are followed up. Eventually, all information will be stored in an electronic data solution. Anonymised information about you will be included in NOBAREV's annual reports.

If you agree to participate in the biobank, some extra blood will be taken for freezing. The blood test is usually taken together with the routine tests and does not involve an extra prick. Extra biobank samples will usually be taken at 1-2 follow-up visits, and maybe 4 times a year in special cases. If samples of tissue, blood, urine or synovial fluid are nevertheless to be taken as part of routine follow-up, it is relevant that material left over is stored in the biobank. A code list will link your health data to the biobank samples.

WIDE CONSENT

Wide consent means that relevant health information and biological material that you provide can be used for future paediatric rheumatology research. Your consent will be stored in an electronic consent register.

USE OF THE INFORMATION FOR RESEARCH

Material in the biobank can be analysed in various research studies which can also include genetic analyses. All future research projects that use your health information or biobank material for research must be approved in advance by the Regional Committee for Medical and Health Research Ethics (REK), but you will only exceptionally be asked again about such use.

In research studies, your identity (name and personal identity number) is replaced with a code (de-identified). The list linking your name to the code is stored in a different electronically secured place (area) than the other information. Only authorised persons have access to this list. It will not be possible to recognise you as a person in any of the scientific

publications that are created. Health information and biological material can also be used by other collaborating research groups in Norway or abroad. This may include countries with worse privacy protection than in Norway, but then the information will always be de-identified. You can contact the doctor responsible for the register, Helga Sanner (for contact information; see below) if you want to know more details about where your information is used.

The research projects will have no direct impact on your treatment or follow-up here and now, but they can provide valuable knowledge that can improve understanding of the disease, diagnostics and treatment in the future.

INFORMATION ABOUT FUTURE PROJECTS

You will regularly receive information about the use of your health information and the biobank material. This will take place in the form of newsletters and/or information posted on the *NOBAREV's information portal* (see below).

COMPILATION OF DATA FROM NOBAREV AND ITS BIOBANK WITH OTHER INFORMATION

To investigate the proportion of children with rheumatic diseases in Norway are actually registered in NOBAREV, the register will be regularly linked to the National Population Register and the Norwegian Patient Register. It is also relevant to compare NOBAREV with biobank with information from patient records, health surveys such as "The Norwegian Mother, Father and Child Survey", other health registers such as e.g. The Cancer Register, the Cause of Death Register, the Medicines Register, the Medical Birth Register, the National Vaccination Register, the Reporting System for Infectious Diseases, the Heart and Vascular Register, the Norwegian Quality Register for Arthritis Diseases and the Norwegian Vasculitis Register with biobank (*see the information portal for a complete overview) – see below*).

PARTICIPATION IS VOLUNTARY

Participating in NOBAREV with the associated biobank is voluntary. It will have no effect on your treatment if you wish that health information or biobank samples are not provided, or if you later wish to withdraw your consent.

APPROVALS AND DURATION

NOBAREV is legally based on Section 3-1 of the Regulations on Medical Quality Registers. The information is stored electronically for as long as is necessary to fulfil the purpose of the register. For the biobank, REK has given prior approval (2014/1437) – the biological material will be stored indefinitely. The managing director at OUS is responsible for data processing for NOBAREV and the associated biobank.

POSSIBILITY TO WITHDRAW CONSENT, RIGHT OF ACCESS, CHANGE AND DELETION OF INFORMATION

You can at any time gain access to which information about and which material from you is stored. You can also, without having to state any reason, withdraw your consent and demand that information be deleted or biological material be destroyed. This does not apply to information already included in analyses or used in scientific publications.

CONTACT DETAILS AND THE INFORMATION PORTAL

If you have questions related to NOBAREV and its biobank, you can contact the doctor/contact person responsible for the Registry: Chief physician and senior researcher/professor Helga Sanner, NAKBUR, Section for Rheumatology, OUS, e-mail: helsan@ous-hf.no . You can also contact the registry consultant Berit Myhrmoen: bermyh@ous-hf.no / Tel.: 22029418 at NAKBUR, OUS.

If you have questions about NOBAREV's privacy policy, please contact the privacy officer at OUS: personvern@oslo-universitetssykehus.no.

Information portal for NOBAREV (scan QR code to the right): https://oslo-universitetssykehus.no/personvern/informasjonsportal-for-deg-som-har-avgitt-bredt-samtykke/norsk-register-for-barnerevmatologi-nobarev

Version 2.1, Sept. 2024

Oslo universitetssykehus

CONSENT TO THE NORWEGIAN REGISTER FOR PAEDIATRIC RHEUMATOLOGY (NOBAREV) AND ASSOCIATED BIOBANK FOR THOSE UNDER 16 YEARS OF AGE

I have read through the information and agree that

1) Relevant health information about me can be registered in NOBAREV and made available for quality assurance and paediatric rheumatology research.

Place and date Your signature

2) Blood samples (and any other biological material) are stored in the associated general research biobank and made available for paediatric rheumatology research.

Place and date Your signature

Oslo universitetssykehus

Patient identification

(The child's date of birth and name, written in block letters)