

Bergen, 23. mars 2022

## Request for participation in the Norwegian Arthroplasty Register

### Background

The Norwegian Arthroplasty Register was established by the Norwegian Orthopedic Association in 1987 to improve the treatment of patients in need of joint replacements. The Norwegian Arthroplasty Register collects data on patients receiving artificial joints in Norway. The register is part of the Norwegian National Network for Arthroplasty and Hip Fractures, Department of Orthopedic Surgery, Haukeland University Hospital, and is approved as a national medical quality register by the Ministry of Health and Care Services. Helse Bergen HF is responsible for data processing for the register. The Data Protection Officer at Helse Bergen has recommended the register in accordance with Article 6, Section 1.a of the EU General Data Protection Regulation, and the Norwegian Privacy Act.

### Purpose of the Norwegian Arthroplasty Register

The purpose of the register is to promote and provide a basis for research on the outcomes of various treatment methods, procedures, and interventions concerning patients. The main goal is to ensure and improve the quality of treatment methods and services offered to patients. In the early 1980s, significant differences in the outcomes of the prosthesis types in use were identified. Unfortunately, some inferior prostheses had been used in many patients before the poor results could be detected. To prevent similar problems in the future, all Norwegian orthopedic surgeons came together in 1987 to create a nationwide prosthesis register. Although prosthesis surgery outcomes are good today, further improvement is still desirable, and some new prostheses and cements are constantly under trial. The register compares new and older prostheses and works to remove poor prostheses, cements, and surgical techniques from the market as quickly as possible. The register will also be used to study the occurrence, cause, and prevention of diseases and injuries leading to joint replacement surgery.

### What does participation mean for you?

Participation in the Norwegian Arthroplasty Register is voluntary and requires informed consent. This means you must sign a consent form before we can register you. The register will collect information such as your personal identification number, diagnosis, reason for surgery, medication use, bacterial tests related to the surgery, and surgical details. This information is collected by the surgeon immediately after the surgery. By signing this form, you are consenting to the collection of this information. We also hope you will fill out a form with questions about your self-perceived quality of life and joint function before the surgery. This questionnaire will also collect information about your height, weight, activity level, education, alcohol use, and smoking habits. We also ask for permission to contact you to complete similar information 1, 6, and 10 years after the surgery. We emphasize that these questionnaires are voluntary. In the future, it may be necessary to collect additional information about your treatment and follow-up from your medical records. For some questions, it may be useful to contact you for follow-up questions. We therefore ask for permission to contact you in such cases.

### Possible benefits and drawbacks

Your participation helps ensure the quality of the treatment you have received, and the knowledge gained from your surgery provides experience that may help others receiving joint replacements in the future. Your participation involves no disadvantages for you, other than the possibility of being contacted for additional information.

### What happens to the information collected about you?

The information registered about you will be stored electronically and used only as described in this information. All data is secured against unauthorized access. Directly identifiable information, including name, personal identification number, or other unique identifiers, is stored separately from the other information in the register and is encrypted. A code links you to your information through a name list. Only authorized personnel associated with the register have access to the name list and can trace the information back to you. Your hospital may receive feedback on your self-reported quality of life, pain, and function. Due to the large amount of data collected, the stored information may appear

indirectly identifiable. However, the data will only be handled by authorized personnel, and results from studies will be anonymous. In the future, the data may be used in projects that are not yet planned, provided they comply with laws and regulations, and with approval from the register's advisory board. Annual national reports will be prepared from the register. Results will also be published regularly at professional meetings and in medical journals. Results based on analyses from the register will not be traceable to individuals. The published studies will be available on our website at [www.helse-bergen.no/nrl](http://www.helse-bergen.no/nrl), where information about ongoing projects is also available.

### **Linkage to other national and/or international registries**

It may be relevant to combine (link) data from the Norwegian Arthroplasty Register with information from other public registries in Norway, such as the National Population Register, NOIS (Norwegian Surveillance System for Healthcare-Associated Infections), the Prescription Register, IPLOS (Individual-based Care and Nursing Statistics), the Norwegian Patient Register, and other national health registers, as well as orthopedic registers like the National Hip Fracture Register, National Ligament Register, and National Pediatric Hip Register. By participating, you also consent to the sharing of data for research in Norway and abroad. The code linking you to your personally identifiable information will not be shared with foreign countries. These may include countries with laws that do not meet European privacy legislation standards. All such combinations require consent and/or prior approval from public authorities, such as the Regional Committee for Medical Research Ethics, the Data Protection Officer, the Norwegian Data Protection Authority, and the Ministry of Health and Care Services.

### **Right to access and delete information**

If you agree to participate, you have the right to access the information registered about you. You also have the right to correct any errors in the information we have recorded. You may request at any time that the information collected about you be deleted from the register without giving any reason. Deleting data will not affect anonymized research files that have already been used.

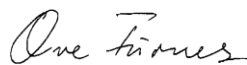
### **Privacy and ethics**

All information will be treated with respect for privacy and confidentiality, in accordance with laws and regulations. Additionally, all information will be handled confidentially, and everyone working with the register is bound by confidentiality regarding the information they become aware of. If you feel that your health information is not being treated in accordance with current regulations, you can also contact the Norwegian Data Protection Authority or the Norwegian Board of Health Supervision.

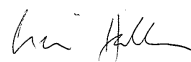
### **Voluntary participation**

Participation is voluntary. If you agree to participate, you will sign the consent form at the bottom of this information. Even if you agree to participate, you can later withdraw your consent without affecting the treatment you receive. If you later wish to withdraw, you can contact the Norwegian Arthroplasty Register (Nasjonalt Register for Leddproteser), Helse-Bergen HF, Orthopedic Clinic, Haukeland University Hospital, Møllendalsbakken 7, 5021 Bergen. Telephone 55973742/55973743 or email [nrl@helse-bergen.no](mailto:nrl@helse-bergen.no).

Best regards,



Ove Furnes  
Senior consultant Ortho Surgeon/professor  
Head of the Norwegian Arthroplasty Register



Geir Hallan  
Senior consultant Ortho Surgeon/professor

**Consent Declaration:**

I have received information about registration in the Norwegian Arthroplasty Register and agree that the surgeon can register information about my surgery. I consent to the data being stored as long as necessary to fulfill the purpose of the Norwegian Arthroplasty Register.

**Signature:**

**Date:**

**Name in capital letters:**

**Personal identification number (11 digits):**

**Address:**