HELSE BERGEN
Haukeland universitetssjukehus
– Alt handlar om mennesket

Versjon 2 (Godkjent 26.06.25)

Request for Participation in the Eating Disorders Registry and Biobank at the Regional Eating Disorders Unit, Helse Bergen

Local Research and Quality Registry for Eating Disorders and Research Biobank for Eating Disorders in Helse Vest

This document is a request for your participation in the Eating Disorders Registry and Biobank. It contains information about the purpose of the registry and the conditions for its use. Please read through the document before signing the consent form. You will receive a copy of the consent form.

Participation is voluntary. If you choose not to participate, you do not need to provide a reason, and this will have no consequences for you now or in the future.

Helse Bergen HF is the data controller for the registry.

Purpose of the Registry

To ensure the best possible treatment for patients with eating disorders, better knowledge about the entire patient group is needed. The purpose of the registry is to ensure that the treatment provided at the Regional Eating Disorders Unit (RAS) is of high quality by documenting and evaluating the treatment given. The registry will also be used for research on eating disorders and their treatment, which may form the basis for improved treatment options in the future.

Contents of the Registry

Registration requires written informed consent from each individual, and we ask for your permission to register information about you in the registry based on your offer of assessment and/or treatment at RAS. The registry will collect information from your medical records and from assessment forms via CheckWare, which are part of the treatment at RAS. Consent to the registry will not involve any extra work for you.

We wish to collect information about you at the start of treatment, after 3 months, and at the end of treatment. If you consent, the following information will be collected:

- *Responses from questionnaires* you complete. As part of the standard assessment and treatment at RAS, you will fill out questionnaires about your background, symptoms, and quality of life related to the illness before, during (3 months), and after treatment. These questionnaires are collected electronically via CheckWare (login via Bank ID) and can be completed either at home or at RAS. Your therapist will review your responses with you and monitor your progress during treatment.

- *Information from your medical records*, such as previous treatments, age, diagnoses, medication use, physical measurements like height and weight, results from blood tests and possibly bone density measurements taken during the treatment process, as well as the treatment measures used and treatment outcomes.

A biobank has been established in connection with the registry for research and quality assurance at RAS, where blood samples are collected for research purposes. Samples are taken at times related to assessment/check-ups. Blood sampling may cause discomfort/pain at the needle insertion site, but other complications are rare. Additional needle sticks are rarely required for research, but extra sample tubes may be collected. Genetic analyses may be performed on the collected material. These analyses are conducted at the group level and cannot provide information about your individual condition.

Conditions for Access and Use of Registry Data and Sample Material

Helse Bergen HF is the data controller for the registry. Data is registered electronically and protected against unauthorized access. All collected information is treated confidentially, and everyone working with registry data is bound by confidentiality regarding the information they access. Your data in the registry will be de-identified and will not include directly identifiable information such as name or personal ID number. A unique code will be used to represent you in the registry. This code is linked to your data through a secure linkage key, which is stored separately. Only a few authorized personnel associated with the registry have access to the linkage key and can trace the data back to you. This is to allow updates and ensure accurate data registration.

To access registry data and/or blood samples from the biobank, researchers must apply to the registry manager and meet formal and scientific criteria. Approved data releases will only include information necessary for analysis and evaluation and will be provided to study personnel. This means all data will be processed without names, personal ID numbers, or other directly identifiable information. Research results will be presented in a way that individuals cannot be recognized.

It may be necessary to analyze the material in laboratories abroad, both within the EU/EEA and in the USA and other countries where data protection laws may be less strict. Helse Bergen HF has procedures to ensure privacy is protected, even when data is transferred outside the EU/EEA. In this context, we ask for your permission to share registry data and/or sample material with researchers in such projects. Any data or sample release will only occur after approval of projects that meet the necessary formal and scientific requirements.

All research projects using registry data must be pre-approved by the Regional Committee for Medical and Health Research Ethics (REK) and other public authorities as required by law. Once a project is approved, you can find information about it on the RAS website at Regional Eating Disorders Unit (RAS) – Helse Bergen HF.

For research purposes, it may also be relevant to combine information from the registry with other data from hospital patient records, biobank, and the following public registries: the National Population Register, Birth Registry, Norwegian Patient Registry, Prescription Registry, Cause of Death Registry, Statistics Norway, SIPEA study (a prospective cohort study of patients admitted to psychiatric emergency units), and the National Quality Registry for Adult Mental Health. Such combinations will only be made if pre-approved by necessary authorities, such as REK, the Data Protection Authority, the Directorate of Health, or the National Insurance Administration.

Reports from the registry will be prepared regularly. Results will also be published continuously at professional meetings and in national and international medical journals. Results based on registry analyses cannot be traced back to individuals. All information will be handled with respect for privacy and in accordance with applicable laws and regulations.

Storage, Access, Correction, and Deletion of Your Data

Your data and biological samples collected from you will be stored in the Eating Disorders Registry and its associated biobank. The storage and processing of this data are conducted in accordance with applicable legislation, and the data will be retained for as long as necessary to fulfill the registry's intended purpose. The retention period is limited but does not have a predetermined end date.

All information associated with the Eating Disorders Registry and biobank is handled with strict confidentiality.

You have the right to access the data registered about you, and to request the correction or supplementation of any information that can be documented as inaccurate or incomplete. You may request to have your data removed from the registry at any time, without the need to provide a justification. You also have the right to request that any biological samples you have submitted to the biobank be destroyed or returned to you.

To withdraw your consent, you may contact the data controller for the registry at the Regional Department for Eating Disorders by telephone at +47 55976820.

Please note that data and materials already generated and potentially published in scientific research cannot be subject to deletion or destruction.

In the event of any irregularities, you may contact the Norwegian Data Protection Authority (Datatilsynet) or the Norwegian Board of Health Supervision (Statens helsetilsyn).

By signing the attached consent form (next page), you confirm that you agree to participate in the Eating Disorders Registry and potentially also in the associated biobank.

Legal Basis for Processing Personal Data

The legal basis for data processing is Article 6(1)(e) of the General Data Protection Regulation (GDPR) and the Regulation on Medical Quality Registries, cf. § 1-4 of the Regulation on Medical Quality Registries.

According to the Royal Decree establishing the Regulation on Medical Quality Registries, the purpose of quality registries to improve health and care services is undoubtedly in the public interest.

Contact Information

Inquiries can be directed to the registry manager at the Regional Eating Disorders Unit, Psychiatric Clinic, Helse Bergen. Phone: 55976820.

Consent Form for the Eating Disorders Registry and Biobank at Regional Department for Eating Disorders, Haukeland University Hospital

I have been informed, through the request to participate in the Eating Disorders Registry and Biobank, about the purpose of the registry, the types of personal data to be recorded, the sources from which the data will be obtained, the procedures for data disclosure, and my rights regarding access, correction, and deletion of data in the registry. The collected samples and data will be used solely for quality assurance of patient care and for research related to eating disorders.

Consent – Local Research and Quality Registry for Eating Disorders

I hereby consent to the inclusion of my personal data in the Eating Disorders Registry, to be stored for an indefinite period. This includes reported data from questionnaires submitted in connection with treatment at the Regional Department for Eating Disorders, collected via CheckWare.

JA	NEI

Consent – Research Biobank for Eating Disorders in Helse Vest

I hereby consent to the collection and indefinite storage of biological samples in the Eating Disorders

JA	NEI

Name (in block letters): …………………………………………………………

National ID number (11 digits) ………………………………………

Place: ………………………

Date: ………………………

Signature: ……………………………………

Date and name of person giving information about the project:

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