REQUEST FOR CONSENT TO PARTICIPATE IN RESEARCH AND QUALITY STUDIES ON MENTAL HEALTH / SUBMIT BIOLOGICAL MATERIAL TO NORSMI BIOBANK

Clinical information about you is collected in the medical records. This information contains clinical information relating to the examination and treatment of your health condition. In addition, blood samples are often taken to find a diagnosis and decide the correct treatment. We kindly request your consent to use any additional material from these samples for future research on mental health. Additionally, we may require the collection of extra samples or a saliva sample to be stored in a general research biobank on mental health.

We ask for your permission to use relevant data about you and your condition to investigate causes, mechanisms and treatment of mental health, on conditions and factors that have an impact on mental health through research. We also ask for your permission to use the results from the various examinations in comparative studies, to study possible common disease mechanisms with other illnesses. For mental health studies, in some cases it will also be necessary to contact you again at a later point. You can find more information about this research on the website https://oslo-universitetssykehus.no/norsmi-biobank. Please contact us if you have any questions.

WHAT INFORMATION WILL BE USED?

Healthcare professionals and researchers at the Acute Psychiatric Department work to improve diagnostics and treatment of mental health disorders, to investigate the importance of mental health in various diseases and to acquire knowledge about causes and disease mechanisms. To be able to do that, it is, among other things, necessary to investigate how the diseases manifest themselves, to investigate how the treatment works and to study test results, investigate laboratory results, as well as images from brain examinations and biological material (blood, saliva, urine and genetic materials). This will be used in research and quality studies.

STORAGE IN GENERAL RESEARCH BIOBANK

If you give your consent, we will store your biological material in a general research biobank. The purpose of this storage is for future research in approved studies on mental health. The Regional Committees for Medical and Health Research Ethics (REK) must approve all use of the biological material in research studies before each study starts. When a study is approved, information about the study will be made available before it starts. The research biobank will be maintained as long as needed, and will thus have no time limit. Professor Ole Andreassen at Oslo University Hospital is responsible for the research biobank. Some studies require national and international collaboration. This may involve transferring data to other countries that have laws that do not have the same General Data Protection Regulations (GDPR) as in Europe. In such cases, we will set the same strict requirements for protection of personal information as in Norway.

PARTICIPATION IN RESEARCH AND QUALITY REGISTRY

If you give your consent, relevant information about you from various sources will be collected and compiled as part of specific research and quality studies within mental health research. This includes sources at the hospitals, specialists and General Practitioners (GPs) (for example, information from medical records, X-rays and laboratory results, internal quality registries, etc.) as well as information from health registries mentioned below. In the specific projects, we will also ask for approval for the use and compilation of relevant information about you with analyses of the biological samples we collect. If you permit, relevant information about you from the individual projects can be stored in a separate quality and research registry for future projects. This registry will initially be maintained until 2035. If necessary, an extended approval will be obtained for.

The consent you give will be stored in an electronic consent registry. You will find information about the use of the research and quality registry and the research biobank on the above-mentioned website. The managing director of Oslo University Hospital has the overall responsibility for processing information about you in the research and quality registry.

INFORMATION FROM HEALTH REGISTRIES

As part of the implementation of specific projects, it may also be necessary to compile personal data about you from

hospitals, specialists, GPs and results from the tests with relevant information from national health registries. This can be registries for cancer, birth, prescriptions, social security, mental health care, immunization, infectious diseases, cause of death, the Norwegian Patient Registry, Statistics Norway's family and social registry, registries for Norwegian Labour and Welfare Administration (NAV) as well as the Registry of the Norwegian Armed Forces Medical Services and Norwegian Registry of Primary Health Care, among other. See full and updated list on the website https://www.fhi.no/en/hd/access-to-data/about-the-national-health-registries2/. If researchers need to gather information from other national health registries or population surveys, it will only take place after approval from REK and/or other authorities as part of the formalisation of specific projects. The managing director of Oslo University Hospital has the overall responsibility for processing your data, and that the privacy legislations are followed.

USE OF BIOLOGICAL MATERIAL

As mentioned, your biological material can be analysed in various studies. This may also include genetic analyses, including genome sequencing. Genome sequencing involves mapping of all or parts of the genetic material. In this context, the genetic analysis will not be done to predict your future illnesses, but for research purposes. For studies involving genetic analyses, it may be necessary to ask you for a new informed consent. The genetic analyses will have specific targets relevant for each research project. In research projects, there is often a need to compare the test results from the biological material with clinical information about you and your state of health. Information can be obtained from the broad research registry for mental health, from medical treatment-oriented registries at hospitals, specialists or GPs.

WHAT DOES PARTICIPATION INVOLVE?

If you give your consent to participate, you allow us to collect and analyse biological information in the general research biobank, as well as to include personal data about you from registries for future projects on mental health and addiction. You are entitled to detailed information in advance about the studies you are included in. Such information will include: i) the purpose of the study, ii) biological material and any genetic tests that are necessary iii) what information should be obtained from your medical record (in and outside the hospital) and various registries to which the data should be linked iv) when the biological material and information will be deleted v) any disclosure of biological material and information to other Norwegian or international research environments and vi) your rights. All studies will be approved by REK. On the web site https://oslo-universitetssykehus.no/norsmi-biobank, you can find information about studies it may be relevant to include you in. If you do not want to participate in any particular study, you can withdraw your consent by contacting the hospital and the contact person for the specific study. If you withdraw your consent, you will receive a confirmation note when your data are erased.

POSSIBLE PROS AND CONS

The research projects will have no direct impact on the choice of treatment for you at the relevant time. However, they can provide valuable knowledge that can lead to a better understanding of mental health in general and to better diagnostics and treatment in the future. As a principle, you will not receive any information about the result of any genetic analyses. If we, contrary to the presumption, detect any genetic variations that could potentially impact your health, you will be contacted.

WHAT HAPPENS TO YOUR PERSONAL DATA AND TESTS?

Both the analyses of the biological material, the data in the research registry and the clinical information about you will be coded (pseudonymized) in studies. This means that your identity (name and national identity number) will be replaced with a code. The list linking your name to the code will be kept secure from the other information. Only authorised personnel have access to the code list and registry. It will not be possible to identify you as an individual in any of the scientific publications.

Your biological material and data may also be used by other collaborating research groups in Norway or abroad. This may include countries with less privacy protection than in Norway, but it that case, the information will always be pseudomized. Please contact the hospital if you want further information about where your personal data is used. According to the GDPR, the data controller at Oslo University Hospital and project principal investigator Ole Andreassen

have independent responsibility to ensure that the processing of your personal data has a legal basis. The legal basis for this project is included in the articles 6 and 9 of the EU General Data Protection Regulation (GDPR).

VOLUNTEERING AND RIGHT TO ACCESS INFORMATION

Participation is voluntary. We cannot store personal data or sample material from you without your written consent. If you later decide to withdraw your consent, there will be no consequences for you or your treatment at the hospital. Stored samples from you will then be destroyed, and information about you deleted.

Information that is already part of a scientific work cannot be deleted, but the information will not be used in any new studies. You have the right to know which personal data that are stored and you can request correction if incorrect personal data has been collected and stored.

CONTACT INFORMATION

If you have any questions, please contact Ingrid Dieset at 22 11 84 20, or principal investigator Ole Andreassen at 23 02 73 50 or e-mail norsmi-biobank@ous-hf.no.

The institution's data protection officer is personvern@oslo-universitetssykehus.no.

APPROVAL

REK has assessed and approved the biobank (2017/1890).

CONSENT

I agree that biological material and relevant personal data can be used for research on mental health.

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Date	Name in CAPITAL LETTERS	Participant signature

(Third party consent when eligible, either in addition to the participant themself or instead of)

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Date	Name in CAPITAL LETTERS	Signature

Patient identification: (unique ID must be provided)