INVITATION TO PARTICIPATE IN A RESEARCH PROJECT (UNDER 16 YEARS)

Variations in brain anatomy in neurodevelopmental disorders – subproject of BUPGEN

This is a substudy under the BUPGEN project, so participation in BUPGEN is therefore a prerequisite. Neurodevelopmental disorders occur in childhood and adolescence and is linked to the delayed or abnormal development of the nervous system. The nature of the neurodevelopmental disorders varies between individuals: some experience great difficulties, whilst others only experience some limited issues.

We know that some genetic variants lead to higher risk of neurodevelopmental disorders, but otherwise we know very little about why some children and adolescents develop differently from others. The goal of this project is to increase our knowledge regarding the cause, course and treatment of some neurodevelopmental disorders, and thus contribute to better treatment and follow-up for children and adolescents with these types of issues. This is done through several different projects organised under the thematic study BUPGEN, for which Oslo University Hospital is responsible.

WHAT IS THE PROJECT ABOUT?

You have previously consented to participate in the BUPGEN study, and data collected from this subproject (MRI investigation) will be included in BUPGEN.

In this substudy, we will take images of your brain with an MRI machine. This will enable us to see what your brain looks like and how it works. It is similar to an x-ray, it does not hurt and is not dangerous, although the machine may be somewhat noisy. During the MRI scan, you will be lying on a bench with a pillow under your head, and the top half of your body will be carefully brought inside the opening of the machine. Some people may feel claustrophobic while inside the machine, but you will be able to communicate with the staff at any point during the procedure using speakers and a mirror. You will also be holding a balloon in your hand that you may squeeze at any point if you want to interrupt the procedure before it is completed. It is also possible to take a break during the test if you become tired or want to move around a little. The MRI scan will take approximately 45 minutes.

This thematic BUPGEN study involves several projects with tests that aim to increase our knowledge of the causes, courses and treatment of neurodevelopmental disorders. The purpose is to find out more about the causes of the disorder, such as innate genetic factors and how the environment plays a role, and which factors that may affect the course of the disease. As one element of this project, we would like to analyse the images from the MRI scan so that we can see whether there are any specific connections between the brain's biology and the disorder. This information will be put together with information collected from the general BUPGEN study, such as genetic material, and data from hospital medical records and health registries, and will be compared with data collected from collaborating studies with similar research aims.

POSSIBLE BENEFITS AND DRAWBACKS OF TAKING PART

The MRI does not hurt, but it is noisy. People who suffer from claustrophobia will not be tested. Beyond the possible discomfort from the collection of blood/saliva samples, as well as a short conversation, there are no drawbacks to participation in this study.

STORAGE IN GENERAL BIOBANK

The blood/saliva samples taken from you will be stored in a general research biobank (BUPGEN) at Oslo University Hospital, for which you have previously provided your consent. Ole A. Andreassen at Oslo University Hospital is responsible for this research biobank, which has an indefinite duration.

RESEARCH AND QUALITY REGISTER

The data registered about you consists of the results from your tests in the general BUPGEN study (diagnosis, severity of symptoms and cognition), somatic information (blood pressure, pulse, neurological findings, etc.) and the MRI images, as well as the genetic tests. We will also collect relevant information from your general practitioner and healthcare centre, as well as data from central public registers.
The data collected from these registers, with the exception of the prescription register, will be stored, together with health report data and data from the biological materials, in the health registers of the thematic study BUPGEN. The managing director at Oslo University Hospital is responsible for the handling of this data.

PARTICIPATION IS VOLUNTARY

Participation in the project is voluntary. If you wish to take part, you will need to sign the declaration of consent on the last page. You may at any point and without providing a reason withdraw your consent to participate. This will not have any consequence for any future treatment. If you decide to terminate your participation in the project, you may demand that your tests and personal data concerning your health be deleted, unless however the personal data concerning health and tests have already been analysed or used in scientific publications. If you, at a later point, wish to withdraw consent or have any questions regarding the project, you can contact Ole Andreassen (tel. 23027350).

WHAT WILL HAPPEN TO MY TEST RESULTS AND HEALTH INFORMATION

Samples that are taken and the data that are registered about you will only be used as described in the BUPGEN research aims. You have the right to access information that has been recorded about you, as well as the right to stipulate that any errors in the information that is recorded be corrected.

The collected results from all participants will, in the long term, give us a better understanding of the causes of these illnesses and how we can treat them. All information from the different tests, including the MR images, will not be accessible by unauthorised individuals. Everyone connected to the project has sworn an oath of confidentiality. The results from the research will be published on a group basis, in such a way that it will be impossible for individuals to be recognised. If you agree to participate in this study, you have a right to know which personal data about you is registered with us, and the right to request correction if the registered information is wrong. If you decide to withdraw from the study, you can ask to have your data deleted, unless the data has already been included in analysis or used in scientific publications. The data will not be used any further. The project is planned to end in 2050, and all sensitive data will be deleted within 2 years of the end of the study.

The purpose of the MRI is not to reveal any disorders or illnesses. We can however not exclude the possibility that we may discover information about you that may be relevant to your health. The images from the MRI are routinely examined by an x-ray specialist physician, in accordance with Oslo University Hospital routines. If any unforeseen discovery is made that should require follow-up, you and your legal guardians will be contacted by a project member. Beyond this, you will not receive any information regarding your MRI scans.

For the purpose of increasing the clinical and scientific value of the project, your biological material, MRI scans and clinical data may also be used by other collaborating research groups in Norway and internationally. This may include countries with less secure data protection laws compared to Norway, but in these cases, your data will always be deidentified beforehand. You may contact the hospital if you would like more detailed information about where and how your information will be used. In accordance with data protection laws, Oslo University Hospital, which is in charge of the controlling and processing of the data, and project leader Ole A. Andreassen have an independent responsibility to

ensure that your data are treated in a lawful manner. This project has a legal basis in accordance with articles 6 and 9 of the EU General Data Protection Regulation (GDPR). When you reach the age of 16 years, you will be contacted by us for further permission to use the collected material.

GENETIC TESTING

The genetic analysis will be conducted on a group level and will not be used to provide specific answers about you, and it will therefore not be possible for individual participants to receive specific results. The collected results from all participants will, in the long term, give us a better understanding of the causes of these disorders and how to treat them.

Results from the analysis of your genetic material will provide information about your particular genetic variant and will be included in genetic tests. The purpose of these kinds of tests is to find the genetic origin of mental illnesses and disorders – in this case, neurodevelopmental disorders and their connection to brain structure and function measured with MRI. The genetic testing that we perform does not have the purpose of reveal any illnesses. We cannot, however, exclude the possibility that we may unintentionally discover information about your genetic material that may be relevant to your health. If this occurs, you will be contacted by a member of the project who will provide information and possible follow-up. Other than this, you will not receive any information about the results from the testing of your genetic material. Despite the confidential and/or deidentified processing of your genetic material, we would like to point out that your genetic material is so unique that it may in theory be identifiable. More information can be found in the BUPGEN information leaflet.

SHARING OF PERSONAL DATA AND TRANSFERRING OF PERSONAL DATA ABROAD

By agreeing to participate in this BUPGEN study, you also give consent to the storage, analysis and processing of your deidentified genetic material (meaning it will be almost impossible to trace back to an individual) by our collaborating partners. By collaborating with other researchers working in the same field, it is easier to find the answers to our research questions. We will always be collaborating with the most appropriate partners at any time. The most important are currently the National Institute of Mental Health (USA), University of California, San Diego (USA), University Hospitals in Bergen, Akershus, Trondheim, Tromsø and Stavanger (Norway), Karolinska Institute (Sweden), University of Copenhagen (Denmark) and deCODE (Iceland). This may also include countries that are not subject to the European GDPR. When collaborating with countries with weaker data protection laws than Norway, we demand compliance with the same strict criteria of data protection. An updated list of collaborators can be provided by Ole Andreassen.

FINANCE AND APPROVAL

We will cover the cost of transport for the additional MRI testing. Ordinary patient injury compensation is applicable. The study and biobank are financed by means of research funding from participating hospitals and universities, regional health trusts, and research councils. They have no economic interest in the research outcomes, but may use them in future patent applications. The project is approved by REC (case no. 2009/932), as well as by the Data Protection Office at Oslo University Hospital. In accordance with GDPR, Oslo University Hospital, which is responsible for the controlling and processing of the data, and project leader Ole Andreassen have an independent responsibility to make sure that the treatment of your data is conducted in a lawful manner. This project has a legal basis in accordance with articles 6 and 9 of the EU General Data Protection Regulation (GDPR).

CONSENT OF PARENTS OR LEGAL GUARDIANS

Legal guardians must provide consent on behalf of children and adolescents under 16 years of age. If the participant is between the ages of 12 and 16 years, we would like them to also sign the consent form to show that they are willing to participate.

CONTACT INFORMATION

If you would like more information, you may call us. You are welcome to call us at any time before or during the study, with questions and/or concerns, or if you would like to withdraw from the study. You can contact project leader Ole Andreassen by calling 23027357 or by email at epost@norment.uio.no. You can also contact Terje Nærland at K.G.Jebsen-center for Neurodevelopmental Disorders by calling 23016057 or by email at terje.narland@medisin.uio.no. More information can be found here: https://www.med.uio.no/klinmed/english/research/centres/kgj-neurodevelopmental-disorders/.

For an electronic version, scan the following QR-code:

CONSENT FOR PARTICIPATION IN THE STUDY

Participant's signature

I consent to participate in the project "*Variation in brain biology in developmental disorders – part of BUPGEN*"

(Place, project participant, date)

Guardian's signature

Guardian _____ _____ _____

Place Date Signature

Guardian _____ _____ _____

Place Date Signature