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

BUPGEN: Neurodevelopmental disorders in children and adolescents – cause and course of illness

Neurodevelopmental disorders occur in childhood and adolescence, and are 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?

We would like to collect data from your medical records from the hospitals that have examined and treated you for neurodevelopmental disorders. It is common for everyone to undergo some examinations concerning any health issues and physical conditions, blood samples and other tests, as well as brain imaging. Additionally, we would also like to store and analyse genetic material from blood samples taken from you. If a blood sample has not already been taken, we would like to take another blood or saliva sample. The study also involves the retrieval of data about you from various health registers (including registers of births, prescriptions, welfare and vaccinations, the National Patient Registry, and Norwegian Statistics Bureau's family and social registry. An updated list can be found online at: https://www.helsenorge.no/en/health-registries/), as well as from your general practitioner and health facilities. You may also be asked at a later time to participate in other projects associated with BUPGEN. If it is necessary to retrieve further information from other central and national health registers or population studies, this will be done after approval has been obtained from Regional Committees for Medical and Health Research Ethics (REC).

Your consent to participate means that data about you will be stored in a research database and used in studies that are investigating neurodevelopmental disorders in compliance with the specific study aims. You can ask to receive detailed information about the various studies prior to your inclusion. This information will include: i) study aims, ii) biological material and possible genetic testing, iii) the specific data about you that will be retrieved from your health reports (in and outside of hospital) and the registries this data will be connected to, iv) when the biological material and data will be deleted, v) the possible sharing of biological material and data with other Norwegian or international research groups, and vi) your rights. All the studies included have been approved by REC.

Information about the various studies that may wish to use your data can be found via this website: https://www.med.uio.no/klinmed/english/research/centres/kgj-neurodevelopmental-disorders/. If you do not wish to participate in a particular study, you can inform the hospital and the contact person for the study. You will receive a confirmation that your wish has been taken into consideration.

STORAGE IN GENERAL BIOBANK

The blood samples taken from you will be stored in a general research biobank (BUPGEN) at Oslo University Hospital. By agreeing to participate in the study, you also consent to the storage of biological material and analysis results in the biobank. Ole A. Andreassen at Oslo University Hospital is the person responsible for this research biobank, which at this point has an indefinite duration. All usage of material for specific studies will be approved beforehand by the Regional Committees for Medical and Health Research Ethics (REC). When a study has been approved, the information about the study will be made available before its start date. It may be necessary to collect more data about you in the future, and we are therefore also asking permission to contact you again in the future for the sake of possible new research projects.

PARTICIPATION IN RESEARCH AND QUALITY REGISTER

If consent is given, the relevant data about you from the various sources in the hospitals (such as patient journals, x-rays, laboratory tests, internal quality registers, etc.) will be collected into a broad research register for research on neurodevelopmental disorders. Additionally, an overview will be created, which will consist of all the different tests that are entered into the research biobank. The register and the overview will initially be maintained until 2035. Thereafter, an extension will be applied for. Your confirmation of consent will be stored in an electronic consent register. You will later receive information about the utilisation of the research and quality register and the research biobank.

POSSIBLE BENEFITS AND DRAWBACKS OF TAKING PART

Apart from some possible discomfort from the collection of a blood/saliva sample, as well as a short conversation, participation does not result in any drawbacks. Participation will not have any consequences for your treatment. The studies may provide valuable knowledge that could lead to better understanding of the different neurodevelopmental disorders, and better diagnostics procedures and treatment in the future. You will not receive any information about the results of the genetic analysis; however, if specific results are found to have any possible implications for your health, you will be offered follow-up and guidance.

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. All information from the various tests will be kept strictly confidential and will not be accessible for unauthorised use. All persons in connection 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. Your biological material and your 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 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 responsible for 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 the particular genetic variant you have and will be included in genetic tests. The purpose of these kinds of tests is to find the genetic origins of mental illnesses and disorders – in this case, neurodevelopmental disorders and their connection to other disorders. We would like to conduct genome-wide analysis, whereby we compare the genetic material of groups of persons with varying levels of ailments, people with and without the disorder of interest (e.g. neurodevelopmental disorders), and parents and siblings of people with these disorders or specific gene variants. With the help of these kinds of analyses, we are attempting to find gene variants that increase the risk of developing the disorder, and we are investigating how combinations of many gene variants increase the risk of developing different conditions.

The genetic testing that we perform are not supposed to 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.

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

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:

Kontaktinformasjon Aktuelt HF

CONSENT FOR PARTICIPATION IN THE STUDY

Participant's signature

I consent to participate in the thematic study "BUPGEN: *Developmental disorders in children and adolescents"*. (If you are between the ages of 12 and 16 years, we would like you to sign the consent form to show that you are willing to participate, but your parents or legal guardians must also give their consent).

(Place, project participant, date)

Guardian's signature

I am familiar with the study and understand what it entails, and I give my child _____(name) permission to participate in this research project.

Guardian _____ _____ _____

Place Date Signature

Guardian _____ _____ _____

Place Date Signature