PARTICIPANTS NEEDED FOR A RESEARCH PROJECT

BRAIN MECHANISMS IN REWARD AND DECISION-MAKING

This is a request for your participation in a research project to shed light on how the activation of different neurochemical systems influences reward and decision-making in the brain. To address this question we will, among other things, use medication that blocks or activates central neurochemical systems in the brain. Professor Siri Leknes from the University of Oslo, Department of Psychology, is responsible for the project. Gernot Ernst, a consultant anaesthetist from Kongsberg Hospital and the University of Oslo, has the medical responsibility.

WHAT DOES THE PROJECT INVOLVE?

Participation in the project involves having to attend 4 research sessions that last approximately three hours. You will complete several tasks, both verbally and on a computer. Some of the tasks are intended to provoke a stress response. Some of the tasks may involve recording video and/or audio. You will also receive a small dose of a medicine intravenously, which involves having two cannulae (small plastic tubes) inserted in a vein, one in each arm. The medicine can be morphine, oxycodone, haloperidol, saline (placebo) or a combination of these. These are known medications that are used clinically in Norway. The medication can have side effects, however as the exposure in this study is short in duration and the dosage is low, any potential side effects are expected to be short lived and mild.

Known side effects include nausea, vomiting, constipation, headache, fatigue, muscular aches, sweating, and feelings of unreality. Other studies have used much higher doses than what we will use, and they have not found any serious side effect in healthy volunteers. Nonetheless, we want to emphasise that you should only participate in the study if you do not have any underlying medical conditions or if you are pregnant. We offer pregnancy tests should you want one. You should avoid driving a car or any other activities that require attention for 6-8 hours after each research session.

In this project we want to collect information about you. We will ask you questions about your physical and mental health, and your drug and alcohol use. We will ask you to provide a urine sample at each research session. During the session, we will measure your performance on several tasks, and ask you about your mood and any side effect of the medication that you might be experiencing. We will measure your heart rate, respiratory rate, collect saliva samples, and collect blood samples to measure the levels of chemical signalling and relevant genetic information.

POSSIBLE BENEFITS AND DOWNSIDES

A possible benefit of taking part in the study is that you can help advance research into the brain's reward systems, which in turn can contribute to a better understanding of and treatment for psychiatric conditions.

The possible downsides to you as a participant include a brief experience of stress related to some of the tasks, temporary side effects of the medication, such as nausea, vomiting, constipation, dry mouth, sweating, feeling dizzy, headache, irritated skin, sedation, or difficulty concentrating. Potential discomfort due to inserting the cannula is to be expected. You cannot drive a car or participate in any other activity that requires full attention for the next 6-8 hours after each research visit.

PARTICIPATION IS VOLUNTARY AND YOU ARE FREE TO WITHDRAW FROM THE STUDY

Participation in the study is voluntary. Should you wish to participate, please sign the consent form on the last page. You are free to withdraw from the project at any point during the study without having to justify your decision. Should you wish to withdraw from the study, you can demand that any of your collected data be deleted, unless the samples have already been sent for analysis or contributed to scientific publications. Should you wish to withdraw, or you have any questions about the project, please contact Siri Leknes, 92622872, siri.leknes@psykologi.uio.no.

WHAT HAPPENS TO YOUR PERSONAL INFORMAITON?

Your personal information will only be used in the way described by the purpose of this project.

You will have insight into what information is registered about you and be entitled to correct any information should it be needed. You will also have insight into the safety measures surrounding data management.

All your information will be anonymised, so that your name and ID number (i.e. “personnummer”) or any other identifying information cannot be linked to your data. A code will be assigned to your data that connects it to your name. Only Siri Leknes and other core members of the project will have access to this code.

Anonymised data will be made available to other researchers upon completion of the project.

Directly identifying information, including video recordings, will be stored on a secure server that is only available to the researchers involved in this project.

Information about you will be anonymised or deleted within five years of project completion.

SHARING OF DATA AND TRANSFERING ABROAD

By participating in this project, you also consent to having your information collected in this study, such as data from the tasks and genetic material, being sent abroad for analysis as a part of research collaboration and publication. After completing the project, your data will be made available for any researchers from anywhere in the world, should they be interested, through a database such as the Open Science Framework. This also includes researchers from countries with laws that do not satisfy European data protection regulations. The project leader will ensure that your information is dealt with in a safe and appropriate manner.

The code that links your identifiable information to your data will not be shared. This means that the shared data is anonymised and cannot be linked back to you.

WHAT HAPPENS TO SAMPLES THAT ARE TAKEN OF YOU?

The samples that will be taken of your will be stored in a research biobank associated with the project. Blood and saliva samples will be stored in biobank number 195241 at Oslo University Hospital, Section of Forensic Medicine. The project leader, Siri Leknes, is responsible for the biobank. The samples will be sent for analysis at the Center for Social and Affective Neuroscience, University of Linköping, Sweden.

The biobank will cease to exist upon completion of the project.

GENETIC ANALYSES

We will analyse genetic material of relevance for reward and decision-making, such as genes associated with dopamine and opioid functioning. We will not examine the risk for any genetic diseases.

Genetic information about the entire genome is unique to you and therefore cannot be anonymised. Information about the entire genome will not be stored with the other information from the project.

INUSRANCE

The patient injury law (i.e."pasientskadeloven") and the product responsibility law (i.e. "produktansvarsloven") apply to all participants in this project.

FOLLOW-UP PROJECT

We want to contact you again so that we can ask you some follow-up questions, should you consent to us doing so.

ETHICAL APPROVAL

The regional ethics committee for medicine and health research has considered this project, and it has approved it (2018/672 REK sør-øst D).

Following new data protection legislation, Arne Benjaminsen (Director of the University of Oslo) and Siri Leknes (responsible for the project) have an independent responsibility to ensure that your information is treated lawfully. The legal foundation for this project is the EU's General Data Protection Regulation (GDPR), article 6a and article 9 number 2, and your consent.

You have the right to complain about the treatment of your data to Datatilsynet.

CONTACT INFORMATION

Should you have any questions about the project you can contact Siri Leknes, 92622872, siri.leknes@psykologi.uio.no.

Data protection officer at the institution is Maren Magnus Voll, personvernombud@uio.no.

I CONSENT TO PARTICIPATING IN THIS PROJECT AND TO MY PERSONAL INFORMAITON AND BIOLOGICAL MATERIAL BEING USED AS IT HAS BEEN DESCRIBED ABOVE

Place and date	Participant's signature
	Participant's name in capital letters