**Letter of Information**
**The use of combined Anodal Transcranial Direct Current Stimulation (tDCS) and cognitive training to modulate decision-making in healthy people.**

**Version 2**
**Date: January 20, 2019**

## BACKGROUND INFORMATION

### Overview of study

You are being invited to participate in a research study conducted by Dr Najat Khalifa, at Queen's University to assess whether transcranial direct current stimulation (tDCS) can influence decision making in healthy people. A member of the research team will read through this consent form with you and describe procedures in detail and answer any questions you may have. This study has been reviewed for ethical compliance by the Queen's University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board.

### What is tDCS?

Transcranial Direct Current Stimulation (tDCS) is a non-invasive brain stimulation technique that involves very weak electrical stimulation to the brain using a battery-operated machine. Stimulation is delivered via two conductive sponges applied to the scalp and a tiny current is passed between them to stimulate specific parts of the brain.

### What will your participation involve?

At the start of the study you will be asked to complete two questionnaires. The first questionnaire (the UPPS+P Impulsive Behaviour Scale) asks you about ways in which you typically think, feel and act. The second questionnaire (Profile of Mood States) asks you about how you currently feel (e.g. tense, tired, depressed, anxious…etc).

You will then take part in two tasks which are administered on a computer. The first task is a simulated gambling game (the IOWA Gambling Task) in which you choose between different decks of cards to win points. You will sit in front of a computer screen on which are shown 4 decks of cards, and you will select a card from any of the 4 decks by clicking on the deck with the computer mouse. Selection of the card will result in you winning or losing points. You will go on selecting cards until you're told to stop. The game will last about 15-20 minutes. Please note that this is a "pretend" gambling situation: you will not actually win or lose any money! The second task (the Stop Signal Task) is a computerized task in which a circle will appear on the computer screen with an arrow inside pointing either to the right or left of the screen. You will use a pad to record your responses by pressing the left-hand button on the pad for arrows pointing to the left or the right-hand button for arrows pointing to the right. The task takes approximately 15 minutes to complete.

You then be asked to take part in a tDCS session. You will be allocated at random to receive either active or sham tDCS. Active tDCS involves delivering a very weak electrical current (2 milli-amperes) to your brain using a battery-operated machine. The stimulation is delivered using two pads applied to the scalp and a tiny current is passed between them to stimulate a specific part of the brain. The actual stimulation will last 20 minutes. During the session you will be asked to repeat the simulated gambling task. Sham tDCS involves following the same procedure as active tDCS but without actual stimulation.

At the end of the session you will be asked to repeat the computer tasks and the Profile of Mood States questionnaire as described above. Finally, you will be asked to complete another tDCS safety questionnaire that asks you about adverse effects from the tDCS stimulation. The entire study will last up to 2 hours.

A member of the research team will provide you with detailed information about the study, and will answer any questions you may have about the study. Once you have understood the precise details of the study explained to you, we will ask to complete a tDCS safety questionnaire to ensure that is safe for you to take part in the study.

**Are there any risks?**
tDCS is considered to be a safe technique, but there are some small risks, which are described below.

The most common side effect (reported by 70% of participants) is that of a tingling sensation under the electrodes. This is present during and shortly after the period of stimulation, and has no adverse effects or risks. Fatigue or tiredness, during the stimulation, is the next common report (by 35% of participants), and this may continue for a short period afterwards. This may occur when prolonged and uninteresting tasks are used during the experiment. Headaches after stimulation may occur in less than 10% of the participants. Headaches are usually mild and can be treated with normal over-the-counter painkillers, if required. There is no evidence that tDCS leads to any change in frequency or severity of headaches. Overall, less than 20% of the participants rated the stimulation procedure as mildly unpleasant and 80% reported that it was not unpleasant. In theory, tDCS might induce seizures, but this has never been reported in the scientific literature.

Your participation will help advance knowledge in the flied. You will also receive $20 for participating in the study.

**Will my taking part in the study be kept confidential?**
All information which is collected about you during the course of the research will be kept strictly confidential, stored in a secure and locked office, and on a password protected database.

The study data collected will be looked at by authorised persons from the Centre for Neuroscience Studies and Department of Psychiatry at Queen's University who are organising

the research. They may also be looked at by authorised people to check that the study is being carried out correctly.

**What will happen if I don't want to carry on with the study?**
Your participation is entirely voluntary and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you withdraw we will no longer collect any information about you or from you but we will keep the information about you that we have already obtained.

**Who is organising and funding the research?**
This research is being organised by the Centre for Neuroscience Studies and the Department of Psychiatry at Queen's University and is being funded by the Department of Psychiatry.

**Publication and Dissemination of the Results**
The results of this study may be published in a scientific journal and may also be presented at scientific meetings. All such data will be presented anonymously so that none of the volunteers can be identified.

**Do you have any further questions?**
If you have any questions please ask the person who gave you this sheet or contact the principal investigator Dr Najat Khalifa (email: nrk2@queensu.ca; Tel, 613-770-2434).

If you have questions regarding your rights as a research participant you can contact:
Dr. Albert Clark, Chair, Queen's University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board: clarkaf@queensu.ca or phone (toll free in North America): 1-844-535-2988.

**CONSENT**

**By signing this consent form, I am indicating that I agree to participate in this study.**

_____ _____
Signature of Participant Date

_____ _____
Signature of a person obtaining consent Date

**STATEMENT OF INVESTIGATOR:**
I, or one of my colleagues, have carefully explained to the participant the nature of the above research study. I certify that, to the best of my knowledge, the participant understands clearly the nature of the study and demands, benefits, and risks involved to participants in this study.

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| Signature of Principal Investigator | Date |