Centre intégré universitaire de santé et de services sociaux du Centre-Sud-de-l'Île-de-Montréal
Québec

Information and Consent Form

Title of the research project :	Extensive characterization of human brain activity under naturalistic stimulations for developing individual artificial brain networks.
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1. Introduction

We are inviting you to participate in a research project. Before accepting to participate in this project, and signing this information and consent form, please take time to read, understand, and carefully consider the following information.

This form may contain words that you do not understand. We are inviting you to ask the principal investigator in charge of the project, or any members of the research project staff, any questions you feel are useful for you, and ask them to explain any word or information that is not clear.

2. Nature and purpose of the research project

To date, the most impressive recent advances on intelligence do not come from neuroscience, but rather from a field of computer science called Artificial Intelligence (AI). We plan to use methods developed in the field of AI to further our understanding of the human brain. More precisely, we plan to use data collected from the images of your brain, to help train an artificially intelligent system to "learn" to behave in a more flexible, human-like manner.

Our hypothesis is that the large amount of brain data generated from the various types of tasks you will perform will help train an artificial network that is capable of performing tasks in a wide range of cognitive domains, as well as being able to adapt quickly to new tasks.

For this project, we intend to recruit approximately 12 participants, men and women that are 18 years and older.

3. Implementation of the research project

3.1 Location of the research project, duration, and number of visits

This research project will take place mainly at the Centre de recherche de l'IUGM du CIUSSS du CSMTL, and the MEG sessions will take place at the Marie-Victorin Pavilion of the Université de Montréal. Your participation in this study will last at least 5 years and will include about 73 visits per year.

3.2 Nature of participation

Our research project will include the following activities. You will be invited to participate in all or some of these activities.

- **3.2.1 Recruitment (1 visit of approximately 45 minutes):**

Upon your arrival, we will ask you to complete a questionnaire that will include some personal information. Some neurological diseases, psychological disorders, hearing or vision problems, past head trauma, as well as taking certain drugs that affect the nervous system may result in you being excluded from the project as these types of factors can distort data recorded during the experiment.

Afterwards, we will use a three-dimensional scanner to take a picture of the surface of your head. This image will be used to create two custom helmets, that will be used during the MRI and MEG scans to reduce artifacts caused by movement.

- **3.2.2 Auditory Task (12 visits of approximately 45 minutes each):**

About once a month you will complete a short battery of auditory tests. The battery of tasks includes the following activities:

1) A visual examination of the external auditory canals.

2) A hearing task (tympanometry) to assess the condition of the middle ear.

3) A sound auditory detection task to check your hearing for high, low and high pitched tones. For this task you will wear headphones and sit in a soundproof cabin.

4) A task of speech recognition in noise. For this task, you will simply need to repeat sentences that will be presented in a background of noise.

Repetition of the auditory battery will verify if there are changes in your hearing throughout your

participation in the research project.

- **3.2.3 Acoustic Mitigation Task (1 visit, approximately 60 minutes)**

We may ask you to participate in this part of the study. If you are selected for the study's acoustic attenuation task, a member of the research team will inform you.

This portion of the study will be a sound detection task, and will check your hearing for low pitched, high pitches, and very pitched tones. The tones will be present through speakers located in the room, and if you hear a tone you will be instructed to press a button.

The detection task will be repeated under the following conditions:

1) With nothing on your head or in your ears.
2) With protective earmuffs.
3) With protective earmuffs, and ear plugs.
4) With protective earmuffs and earplugs, and your personalized helmet.

- **3.2.4 Structural MRI (4 visits, approximately 60 minutes each):**

These visits will take place approximately every 3 months, and during the meetings we will take pictures of your brain. During the acquisition of these images, you will have to remain motionless.

- **3.2.5 MRI with tasks (46 visits, approximately 60 minutes each):**

MRI sessions with tasks will take place approximately once a week. For two of the tasks you will have to watch videos or play video games for about 30 minutes, while remaining motionless. For the other tasks, we will ask you to do one of the following tasks, which will last about 15 minutes:

1) **Language** - The language task will consist of looking at words on a screen, and making a choice between two or three options, depending on task. The exact task will be explained to you by one of the members of the research team.

2) **Reading** - During this task, you will be asked to read aloud a text that will be shown on the screen. The exact task will be explained to you by one of the members of the research team.

3) **Image** - The image task will consist of viewing images on a screen and making a choice between two or three options, depending on the task. The exact task will be explained to you by one of the members of the research team.

4) **Memory** - The memory task will consist of looking at images of known objects and trying to memorize these images and their position on the screen. Afterwards, you will have to remember objects and their position. The exact task will be explained to you by one of the members of the research team.

5) **Video Games** - The video game task will consist of playing an assortment of video games in the scanner. This task might not be paired with other tasks, and as such might last up to 60 minutes.

6) **Resting state** - The task simply requires you to relax watching a calm video with music. During this rest phase, images of your brain will be taken during two 7-minute periods for a total of about 14 minutes.

7) **Eye movements** - A recording of the movement of your eyes will be made using a small camera.

8) **Facial Expressions** - A recording of the movements of your face will be acquired to qualify your facial expressions and will be performed at using a small camera. Small adhesive markers may be placed on your face to quantify your head motion during your MRI.

In addition, before each MRI, two sensors will be placed on your foot, to record your skin responses. Also, two sensors will be placed on your ankle to record your pulse and three sensors will be placed close to your heart for record your heart rate. A belt will be placed on your chest to measure your

breathing.

- **3.2.6 Motion Task (2 visits approximately 60 minutes):**

We may ask you to participate in this part of the study. If you are selected for the motion task, a member of the research team will inform you. The purpose of this task is to quantify the amount of head motion during a scan. Small adhesive papers will be placed on your head, and you will be scanned with and without your headcaset, while performing various tasks described above. These tasks include; resting state, reading, videos and video games.

- **3.2.7 MEG (10 visits, approximately 120 minutes each):**

The MEG visits will be carried out in the same way as the MRI with tasks visits, and the same tasks and activities will be carried out.

- **3.2.8 Pilot Project (10 visits MRI and 1 visit MEG, approximately 60 minutes each):**

We may ask you to participate in the Pilot Project. If you are selected for this part of the study, a member of the research team will inform you. In all the tasks below, the exact task will be explained to you by one of the members of the research team, and you will have the opportunity to practice the task prior to scanning.

The Pilot Project consists of the following 7 tasks:

1) **Gambling** - The task will consist of a card guessing game where you will have to guess if the number on card, represented by a "?" on the screen, is above or below 5. If you guess correctly, you earn 1 dollar, if not you will lose $ 0.50, and if the number is exactly 5, you neither win nor lose money.

2) **Motor** - The task will consist of pinching your index and thumb of your left or right hand, to squeeze your left or right toes, or to moving your tongue. Participants will receive a visual signal indicating which movement to perform.

3) **Language Processing** - The task will consist of listening to an auditory story, and answering a question about the content of the story, or listening to a mathematical problem with multiple choice answers.

4) **Social Cognition** - The task will consist of looking at short video clip and making a decision on how the objects in the clip were interacting.

5) **Relationship processing** - The task will have two conditions. In the first category, «relationship processing», 2 pairs of objects will be presented on the screen, one pair at the top of the screen and the other pair at the bottom You will be asked to decide whether the upper pair and lower pair differ, or not, on the same dimension (i.e. shape or texture). In the second category, «control matching», you will see two objects at the top of the screen and one object at the bottom of the screen and a word in the center of the screen. You will be asked to decide whether the bottom object has one of the characteristics, either the shape or the pattern, of one of the two higher objects.

6) **Emotion Processing** - The task will consist of examining faces or shapes and choosing which of the shapes at the bottom of the screen corresponds to the target face or shape at the top of the screen.

7) **Working Memory** - The task will consist of looking at images of tools, places, or body parts, and to make an association between a target image and the image shown on the screen.

8) **Resting state** – During this task you will be instructed to keep your eyes open, not to fall asleep, and look at fixation cross in the middle of the screen.

3.3 Description of the magnetic resonance imaging (MRI) apparatus.

Magnetic resonance imaging performed in research setting provides images of the body and the brain, as well as how they work. For its part, functional magnetic resonance imaging (fMRI), can be used to see areas of the brain that become active when a person is asked to perform a task. Indeed, when the person performs the task requested, there is an increase in blood supply to the part of the brain that controls this activity. The blood supply causes a change in the signal sent by the brain and this modified signal may be detected by the device.

To perform the MRI, no substance will be injected. You will lie on a mattress that will slowly be slid into a large tube. The tube is open at both ends. An intercom system allows you to communicate with the medical imaging technologist if necessary. For your comfort, we will ask you to wear either headphones or protective plugs that will be placed in your ears to reduce loud noises emitted by the device. While the device is running, it is important to remain still. To ensure your comfort, and help you stay still, a personalized styrofoam headcase will be placed around your head.

3.4 Description of magnetoencephalography (MEG).

The MEG scanner is a device that records magnetic activity of the brain. In order to avoid recording environmental noise, the recording apparatus is placed in a small closed room that deflect the ambient magnetic fields. Although you will be alone in this closed room, you will always be able to communicate with the technician via the intercom.

During the recording of the MEG you will have to stay still. To ensure your comfort, and help you stay still, a personalized styrofoam headcase will be placed around your head.

EEG-type sensors will be used to monitor the movements of the eyes during the experiment, as well as provide links between the electrophysiological activity, and the magnetic activity of the brain during the task.

Prior to the application of the sensor, a technician will gently scrub the surface of your scalp, at the locations where the sensors will be placed, using a using a mixture of isopropyl alcohol swab and an abrasive gel. They will then place the sensors on your scalp using a conductive paste.

Additionally, in order to ensure that the analyses as precise as possible, we will need to know the exact location of the tracking coils placed on your head. To locate the position of these coils, the technician will take a picture of each of them. Only the principal researchers will be able to access these photos, and they will only be used for analyses. Note that these photos will be kept in digital format on a secure server.

3.5 Property of the data.

At all times, you will remain the owner of your data. Under no circumstances will your data be sold, and your data will only be used for research purposes.

The director of the Courtois Neuromod database will act as trustee for the data that will be collected in the database. That is, in accordance with the management framework of the Courtois Neuromod database, he will be responsible for the storage, custody and security of the data collected. In addition, he will be responsible for the distribution of data to researchers who are members of the Courtois Neuromod database.

4. Incidental finding

Although they are not subject to a formal medical assessment, the results of all the tests, examinations, and procedures performed in this research project may highlight previously unknown problems, this is known as an incidental finding. This is why, in the presence of a particularity, the researcher responsible for the project will call you and ensure follow-up.

5. Benefits associated with the research project

Although we cannot ensure it, it is possible that you derive a personal benefit from your participation in this research project. In addition, the results obtained will contribute to the advancement of scientific knowledge in this field of research.

6. Risks associated with the research project

6.1 Auditory tasks

According to current knowledge, your participation in auditory hearing tasks will not put you at risk.

6.2 Magnetic resonance imaging (MRI).

According to current knowledge, your participation in research-based magnetic resonance imaging will not pose a medical risk to you if you do not have any contraindications.

Due to the power of the magnetic field emitted by the device, it is necessary to take certain precautions. Therefore you must complete a detailed questionnaire to detect any contraindications, for example; the presence of a pacemaker, aneurysm clip, prosthetic metal, prosthesis or heart valve clip, presence of metal in the eye or body, tattooing, piercing, dental pins or if you suffer from claustrophobia. The rigorous verification for contraindications will be done by the medical imaging technologist.

In addition, the conditions imposed by the use of the device can cause discomfort from having to remain stationary. You may also feel some type of stress.

We would also like to remind you that the operation of the MRI machine generates significant noise. To avoid any discomfort, we will ask you to wear protective earbuds, that also act as headphones, as well as protective earmuffs on your ears, with the aim of significantly reducing the noise that is emitted by the device.

To avoid negative consequences for your hearing health, and to make sure that you do not have any changes in your hearing, during the duration of your participation in this research project, we will perform, approximately once a month, a short battery of auditory tests. In the event that there is a change in your hearing, you will be informed immediately.

6.3 Magnetoencephalography (MEG).

According to current knowledge, your participation in magnetoencephalography will not put you at risk.

During the MEG visits, measures will be taken to overcome any possible inconveniences that may be caused by the repetition of stimuli: fatigue, discomfort related to immobility and sustained attention. Further, the presentation of stimuli will be regularly interrupted, allowing you to relax.

7. Risks associated with pregnancy

Participation in this research project may involve risks, known or unknown, for pregnant women, unborn children, or breastfed infants. This is why pregnant, or breastfeeding women can not participate in this project.

Women who are likely to become pregnant will have to undergo a pregnancy test before the MRI scan, and they will only be able to participate in this project if the result of the pregnancy test is negative.

8. Voluntary participation and possibility of withdrawal

Your participation in this research project is voluntary. You are therefore free to refuse to participate. You can also withdraw from this project at any time, without giving reasons, by informing the research team.

The researcher responsible for this research project, the Comité d'éthique de la recherche vieillissement-neuroimagerie, or the granting agency may terminate your participation without your consent. This can happen if new discoveries, or information indicate that your participation in the project is no longer in your interest, if you do not follow the guidelines of the research project, or if there are administrative reasons to abandon the project.

If you withdraw from the project, or are removed from the project, the information, and material already collected for this project will nevertheless be retained, analyzed or used to ensure the integrity of the project.

Any new knowledge gained during the course of the project that could have an impact on your decision to continue to participate in this project will be communicated to you shortly.

9. Constitution, preservation, access to the database and confidentiality.

During your participation in this research project, the researcher in charge of this project, as well as the members of his research staff will collect, in a research file, information about you that is necessary to meet the scientific objectives of this research project.

This information may include information about your past and present health, lifestyle, and the results of all tests, examinations and procedures that will be performed. Your file may also include other information such as your name, gender, education, date of birth and ethnicity.

All information collected as research data will be securely stored in the Courtois Neuromod database, housed at the IUGM Research Center, in accordance with the database management framework of the Courtois Neuromod database.

Your research data will remain confidential within the limits provided by law. In order to preserve your identity, and the confidentiality of the information, you will only be identified by a coded ID. The coded ID linking your name to all of your data will be kept by the designated researcher responsible for this research project.

The Courtois Neuromod database will provide a platform to researchers who are members of the Courtois Neuromod database to carry out research projects. All of these research projects will first be evaluated and approved by the Ethics Committee on Aging-Neuroimaging Research prior to their completion. The Ethics Committee on Aging-Neuroimaging Research will also follow up.

The research data in the Courtois Neuromod database will be shared with different researchers who are members of the Courtois Neuromod database. This transfer of information means that your research data could be transmitted to countries other than Canada. However, the researcher responsible for this research project will respect the confidentiality rules in force in Quebec and in Canada, in all countries.

Your research data will be kept as long as it can be useful for the advancement of scientific knowledge. When they are no longer needed, your research data will be destroyed. In addition, note that at any time, you may request the non-use of your research data by contacting the researcher responsible for this research project. In this case, the information already obtained under this project will be retained for as long as necessary to comply with the regulatory requirements, but no new projects will be carried out with your research data.

For surveillance and control purposes, your research file as well as the Courtois Neuromod database may be consulted by a person mandated by the Comité d'éthique de la recherche vieillissement-neuroimagerie or by the institutions or by a person mandated by an authorized establishment. All of these people, and organizations adhere to a privacy policy. You have the right to consult your research file to verify the information collected, and have it rectified if necessary.

10. Participation in subsequent studies

Do you agree that the researcher in charge of this research project, or a member of his research staff contact you to propose to participate in other research projects? Of course, during this call, you will be free to accept or refuse to participate in proposed research projects. ☐ **yes** ☐ **No**

11. Potential commercialization

The results of this project, derived in part from your participation, could lead to the creation of commercial products and generate profits. However, you will not get any financial benefit.

12. Financing the research project

The researcher responsible for this research project received funding from the granting agency to complete this research project.

13. Compensation

As compensation for expenses incurred as a result of your participation in the research project, you will receive $100 for each MEG visit, and $50 for all other visits. If you withdraw from the project, or if your participation ends before it is completed, the compensation will be proportional to the duration of your participation.

In addition, participants who have completed the gambling task will be compensated for the money earned. This amount will vary between zero dollars and five dollars.

14. In case of injury

If you suffer any prejudice due to your participation in the research project, you will receive all the care and services required by your state of health.

By agreeing to participate in this research project, you do not waive any of your rights, and you do not release the researcher responsible for this research project, the granting agency, and the establishment of their civil and professional liability.

15. Procedures in the event of a medical emergency

Please note that the IUGM is not an acute care hospital that provides emergency services that has a physician on site 24 hours a day. Therefore, in the event of a medical condition that would require immediate care, first aid will be provided by existing staff, and arrangements will be made to transfer you, if necessary, to the emergency room of a nearby hospital.

16. Identification of resource personnel

If you have any questions or problems related to the research project or if you wish to withdraw from it, you can contact the researcher responsible for this research project, Pierre Bellec, or Julie Boyle from the research team at next number 514.340.3540 extension 3306.

If you have any questions about your rights as a participant in this research project, or if you have any complaints or comments to make, you can contact the Service Quality and Complaints Commissioner of the CIUSSS du Centre-Sud-de-l'Île-de-Montréal, at 514.593.3600.

17. Monitoring the ethical aspects of the research project

The Comité d'éthique de la recherche vieillissement-neuroimagerie has approved the research project and will be monitoring it. For any information, you can reach the Committee by phone at 514.527.9565, ext. 3223 or by email at the following address: karima.bekhiti.ccsmtl@ssss.gouv.qc.ca

Consent

Title of the research project: Extensive characterization of human brain activity under naturalistic stimulations for developing individual artificial brain networks.

1. Participant consent

I have read the Informed Consent Form. I was explained both the research project, as well as the Informed Consent Form. My questions were answered, and I was given the time to make a decision. After reflection, I agree to participate in this research project under the conditions stated therein.

I agree to participate in this research project under the conditions set out in this Informed Consent Form. A signed and dated copy of this has been given to me.

Name and signature of the participant Date

2. Signature of the person who obtained the consent, if different from the investigator in charge of the research project.

I have explained to the participant both the research project, as well as this Informed Consent Form and I have answered all the questions he/she asked me.

Signature of the person who obtained the consent Date

3. Signature and commitment of the researcher responsible for this research project

I certify that this Informed Consent Form was explained to the participant and the questions they had were answered.

I agree with the research team to respect what has been agreed upon in the Informed Consent Form and to provide a signed and dated copy to the participant.

Signature of the principal investigator of this research project Date