

**LETTER OF INFORMATION AND CONSENT**

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**PATIENT VOLUNTEERS**

**“Candidate Neuronal Circuits in Mental Illness”**

Principal Investigator: Peter Williamson, **MD**.

INVITATION TO PARTICIPATE IN RESEARCH

The pronouns ‘you’ and ‘your’ should be read as referring to the participant rather than the parent/legal guardian who may be signing the consent form for the participant.

You are being invited to voluntarily participate in a research study looking at the way the brain changes in mental illness. The purpose of this letter of information and consent is to give you the information you need to make an informed decision about whether or not you would like to participate. It is important that you know what the research involves. Please take the time to read this carefully and ask questions if you would like to understand some part of it better. Please feel free to ask the research staff any questions you may have about the study at any time. You will be given a copy of this letter of information and consent once it is has been signed.

PURPOSE OF THE STUDY

You are being asked to participate in a research study examining how the various parts of the brain are interconnected while at rest (not performing any particular task). In order to measure your brain activity, you will then have special tests called magnetic resonance spectroscopy and functional magnetic resonance imaging scans. Magnetic Resonance Spectroscopy allows researchers to obtain [biochemical](http://en.wikipedia.org/wiki/Biochemistry) information about the characterization of [tissues](http://en.wikipedia.org/wiki/Tissue_%28biology%29) in the brain. Functional magnetic resonance imaging, or fMRI, is a technique for measuring which parts of the brain are involved in a particular mental process or activity

Interestingly, the brain is never completely at rest. Even when we are resting or not performing any specific task, our brain is busy preparing future actions, examining its own status and feelings, reminiscing on past events and talking to itself (inner monologue). All this activity seems to involve the same set of brain regions in healthy people. This is called the default network of the brain. The default network is a network of brain regions that are active when an individual is not focused on the outside world and the brain is at wakeful rest. [Brain](http://www.scholarpedia.org/article/Brain) connectivity refers to a pattern of interactions between distinct units within a nervous system.

It is thought that people with mental illnesses such as schizophrenia or depression may have a different pattern of connectivity in the default network and that this may relate to some of the symptoms of those diseases.

By comparing people with mental illness with people who have never experienced mental illness, we can learn about the subtle abnormalities in default network connectivity. This improves our understanding of mental illness and ultimately helps devise new treatment strategies or improve existing one.

This letter is for people who are experiencing mental illness. There is a separate letter for the people without mental illness.

EXPECTED DURATION OF STUDY AND NUMBER OF SUBJECTS PARTICIPATING

This study will involve approximately 93 participants in the study, specifically 31 healthy control participants, 31 first episode, never-treated patients with schizophrenia and 31 first episode, never-treated patients with depression and the study will be conducted over a period of five years. The MRI scan will take place at the Centre for Functional and Metabolic Mapping within the Robarts Research Institute attached to the University Hospital. For routine patient care a 1.5 tesla MRI machine is used in clinical settings for our research purposes we will be using a 3 tesla and 7 tesla MRI machine. After the initial MRI scan is completed, participants will be asked to return to repeat the imaging procedures in about 4-6 weeks and again in approximately 36 months.

ELIGIBILITY

You must not participate in this study if you are claustrophobic, have any cranial clips, have a cardiac pacer, or have any other metallic implants except dental fillings. Women of childbearing potential must be using a reliable means of birth control. If you have any doubts about whether or not you are pregnant, you must not participate.

PROCEDURES

If you take part in this study you will have the following evaluations. These procedures have been designed to help address the research objectives described previously. The only reason you would have them now is as part of this study. As part of the study, you will be interviewed for up to two hours to see if you are eligible for the study. If you are eligible you will be asked to complete a metal screening form and you will be provided with an appointment time for the MRI brain scan. The metal screening form will be reviewed with you again before entering the high field environment of the MRI scanner. During the MRI scan you will be placed on a table that will move inside the test machine, which basically resembles a large doughnut, with the table sliding through the hole. There will be a session of about two to three hours when you will be lying on the table while the machine gathers data. There will be at least one break of fifteen minutes. During this time you will be exposed to magnetic fields and radio waves. You will not feel either. You will, however, hear repetitive tapping noises that arise from the magnets that surround you. You will be provided with earplugs that you will be required to wear to minimize the sound and protect your hearing. There are no known significant risks with this procedure at this time because the radio waves and magnetic fields, at the strengths used, are thought to be without harm. The exception is if you have a cardiac pacemaker, or a metallic clip in your body (e.g., an aneurysm clip in your brain), have severe heart disease, body piercings, tattoos containing metallic ink or slow release pharmaceutical skin patches. There is a possibility that you will experience a localized twitching sensation due to the magnetic field changes during the scan. This is not unexpected and should not be painful. However, you can stop the exam at any time. The magnetism and radio waves do not cause harmful effects at the levels used in the MRI machine. However, because the MR scanner uses a very strong magnet that will attract metal, all metallic objects must be removed from your person before you approach the scanner.

You will be able to get up and walk around during the break. For most of the scan you will be asked to just lie quietly. At other points during the scan you will be asked to perform tasks such as looking at a target on a screen in front of you or closing your eyes. The metal screening form you completed will be reviewed again before entering the high field environment of the MRI scanner.

RISKS AND DISCOMFORTS

HIGH MAGNETIC FIELD MRI SCANNER

Part of your participation in this study will involve a research test with Magnetic

Resonance Imaging (MRI) system, a common medical diagnostic tool that uses a strong

magnetic field, a low frequency magnetic field, and a radio frequency field. No X-rays

are used. As with any technology there is a risk of death or injury. For MRI the risk of

death is less than 1 in 10 million and the risk of injury is less than 1 in 100,000. These

risks do not arise from the MRI process itself, but from a failure to disclose or detect MRI

incompatible objects in or around the body of the subject or the scanner room. It is

therefore very important that you answer all the questions honestly and fully on the MRI

screening questionnaire. Almost all the deaths and injuries related to MRI scans have

occurred because the MRI operator did not know that surgically implanted metal

hardware (such as a cardiac pacemaker) was present inside the subject during the MRI

scan. Other remote risks involve temporary hearing loss from the loud noise inside the

magnet. This can be avoided with ear headphone protection that also allows continuous

communication between the subject and staff during the scan. For comparison, the risk of

death in an MRI is similar to travelling 10 miles by car, while the risk of injury during an

MRI is much less than the risks associated with normal daily activities for 1 hour. You

may not be allowed to continue in this research study if you are unable to have a MRI

scan because, for example, you have some MRI incompatible metal in your body, you

may be pregnant or attempting to become pregnant, or you may have a drug patch on

your skin that contains a metal foil. Should you require a medically necessary MRI scan

in the future, the final decision as to whether you can be scanned will be made by a

qualified physician considering all the risks and benefits.

INCIDENTAL FINDINGS

The MRI experiments carried out for this study are performed solely for scientific

purposes.  The data which is collected is not optimized to make clinical diagnoses, and

the research team involved in these experiments are not trained to make medical

evaluations.  By participating, you agree that the experimenters are not expected to arrive

at a clinical interpretation of the data collected.

Nevertheless, there is a small possibility that a potential abnormality might be observed –

otherwise known as an incidental finding.  If this occurs you will be notified of the issue

by the principal investigator of the study who will assist you with your options for

following up. Investigators are not responsible for the outcome of medical follow-up or

for any incurred costs during medical follow-up.  By participating, you agree to the

possibility of being informed about a potential incidental finding, according to the above-

described procedure. If you do not agree to the potential risk of an incidental finding you

should not participate in this study.

EXCLUSION CRITERIA

**Magnetic Resonance Imaging**: If you have any history of head or eye injury

(such as a cardiac pacemaker), if you have severe heart disease (including susceptibility

to heart rhythm abnormalities), or [for women] if you could be pregnant, or have an

intrauterine device, you should not have an MRI scan. Additionally you should not have

a MRI scan if you have conductive implants or devices such as skin patches, body

piercing or tattoos containing metallic inks because there is a risk of heating or induction

of electrical currents within the metal element causing burns to adjacent tissue.

**Substances**: Please report any medications you are taking or plan to take during the study

(health food store supplements, stimulants, pain medication, etc) as these may affect the

brain and prevent you from participating in the study.

BENEFITS

There are no personal benefits from participating in this research. However, your participation may provide us with a better understanding of the nature of mental illness which may lead to earlier intervention and the development of better treatments.

RIGHT TO WITHDRAW FROM THE STUDY

Participation in this study is voluntary. You may refuse to participate, refuse to answer any questions or withdraw from the study at any time with no effect on your future care. You do not waive any legal rights by signing the consent form.

If you are participating in another study please inform our research team to ensure that there is no problem with participating in both studies. Participation in this study will not affect your ability to participate in future research studies.

CONFIDENTIALITY

Any information that is collected about you during the study will be kept confidential unless disclosure is required by law. If the results of the study are published, your name will not be used and no information that identifies you will be released. Representatives of the University of Western Ontario Health Sciences Research Ethics Board may require access to your study-related records or may follow up with you to monitor the conduct of the study. Your research records will be stored in a locked filing cabinet in a secure office. Absolute confidentiality cannot be guaranteed, as we may have to disclose certain information as required

by law. If the research records are demanded by law, as from a subpoena, your confidentiality cannot be guaranteed but your privacy will be protected to the maximum extent allowed by law.

ALTERNATIVES TO STUDY PARTICIPATION

An alternative to the procedures described above is not to participate in the study and continue on just as you do now. If you decide not to participate or if you withdraw from the study before it is completed, there will be no negative consequences related to your receiving any future treatment in this facility.

CONTACT PERSON FOR PARTICIPANTS

Please contact the study coordinator or Principal Investigator at (519) 663-3032 **t**o report concerns, or ask questions relating to the research study. If Principal Investigator or research staff member is not in the office, please feel free to leave a voicemail message. Your call will be returned within the next business day.

FURTHER QUESTIONS

If you have any further questions about this study you may contact: Dr. Peter Williamson at (519) 663-3032. If you have any questions about the conduct of this study or your rights as a research subject you may contact:

Dr. David Hill, Scientific Director, Lawson Health Research Institute at (519) 667-6649.

Or

The Office of Research Ethics at (519) 661-3036 or by email at [ethics@uwo.ca](mailto:ethics@uwo.ca).

REIMBURSEMENT FOR PARTICIPATION

You will be reimbursed up to $50.00 for cost associated with your participation in the study at each scan (i.e. parking, mileage etc.). Should you have any questions, please feel free to contact Dr Williamson at the telephone number listed above.

This letter of information is yours to keep.

CONSENT FOR HEALTHY VOLUNTEERS

**“Candidate Neuronal Circuits in Mental Illness”**

I have read the Letter of Information, and have had the nature of the study explained to me and I agree to participate. All questions have been answered to my satisfaction.

Name of Subject (print please)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Subject Date

Name of Guardian (if applicable) (print please)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Guardian (if applicable) Date

Name of person responsible for obtaining this consent

(print please)

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Signature of person responsible for obtaining this consent Date