Informed Consent Template for Magnetic Resonance Imaging Studies

Note: Items that should be modified (inserted/removed/reworded) to reflect the study requirements are in brackets. This document has been approved by the head of the CAMH MRI Unit and the director of the CAMH Research Imaging Centre (2013_0418).

Magnetic resonance imaging (MRI) is a technology that uses strong magnetic fields (“magnetic”) and radio frequency fields (“resonance”) to produce detailed pictures of soft tissues in the body, including the brain. For this study, we will be using MRI to take pictures of your brain’s structure, [and] [your brain’s function] [and] [to measure your brain’s neurochemistry].

Because MRI uses strong magnetic fields, we need to make sure you do not have certain metal objects in your body or with you when you enter the MRI room. You will be asked to change into hospital pants and gown when you arrive at the MRI facility. Your clothes and all personal items (e.g., watches, jewelry, wallet, cell phone) will be stored in a secure locker. The MR technologist will talk with you before the scanning session to answer any questions, and to make sure it is safe for you to go into the MRI. [If appropriate, e.g., TMS studies using navigation: Before you go into the scanner, we will place some markers on your face and head that will help us identify the location of the brain region we will be targeting when you come for the TMS part of the study.]

The MRI machine looks like a big doughnut, and you will lie down on a bed with your head and shoulders in the tunnel made by the “doughnut hole”. We will put some pillows around your head to keep it from moving and then ask you to stay very still while we scan your brain to get the pictures. You should try to remain as still as possible during the scans. Movements will not be dangerous to you in any way, but will blur the picture of your brain. For [each/the] MRI session, you will need to hold still in the machine for [time], [for studies booking >1hr: but we can give you some small breaks to relax if you need them]. The MR technologist will be able to observe you at all times. You will be able to contact the MR technologist at any time during the scan session for any reason.

You will hear moderately loud knocking or beeping sounds when the MRI machine is scanning. You will be given ear protection to wear in the scanner. Different types of scans will make different types of sounds, which is normal for MRI. The technologist will talk to you before each scan starts. There will be a mixture of very short scans and some longer scans (up to [longest scan duration] minutes each).

[For fMRI studies: Functional MRI measures your brain’s activity. For some of the scans we will ask you to [rest and let your mind wander with your eyes open/closed], or [watch some pictures/video or listen to some sounds] and [press a button to certain pictures or sounds] so we can measure your brain’s activity. [Insert additional information specific to the study as appropriate – e.g., general task description if not described earlier]. These scans will take about [time] minutes each and you will complete [number] of them.]
Risks.

**Metal Objects.** Before you can participate in an MRI study, we need to make sure it is safe for you to do so. Because certain metal objects may lead to injuries during the MRI procedure, we will ask you to answer questions about any metal implants or objects you might have in your body and the location of any tattoos. If you have any metal implants or objects that are not safe for the [field strength] MRI at [hospital name], you will not be allowed to be scanned. Some objects that are not safe for MRI include cardiac pacemakers, metal fragments in the eye, aneurysm clips in your brain. If there is a strong chance you may have metal fragments in your eyes, you will need to provide an x-ray report of your eyes before you can be scanned. The research study staff and the MR technologist will work together to make sure you will be safe in the scanner. We will also ask whether you are extremely uncomfortable in enclosed spaces (claustrophobia). [Optional: The study physician may prescribe a sedative for you to help you relax during the MRI session. Because you may feel sleepy after this medication, the study physician or nurse will let you know when it safe to leave. You will not be allowed to drive, so you should make other arrangements.]

**Long-term risks.** Based on the use of MRI in medicine for over 20 years, most experts believe there are no long-term negative health effects caused by the magnetic field strength used in this study. This MRI study does not involve any form of ionizing radiation or injections.

**Other risks.** Some people may feel uncomfortable lying still in the confined space of the MRI scanner, tingling sensations are felt by some people during certain scans or you may feel dizzy for a few minutes at the end of the MRI study. These are infrequent, but expected sensations.

It is important you understand that you will be able to contact the technologist at any time during the scan. You may ask to be taken out of the scanner for any reason without any penalty or consequences.

**Unexpected findings.** The possibility of unexpected or incidental findings carries with it some risks. Research scans are not designed to be used for diagnosis. In the unlikely event an atypical finding is seen on your MRI scan, we may ask a radiologist or other qualified health professional to look at your scan. By signing this consent form, you agree to allow us to release the scan for review of any unexpected findings. Your identity will not be revealed. If the qualified professional recommends further tests to determine the nature and significance of any incidental findings on your MRI scan, we will contact you to help you arrange medical follow-up.

**Pregnancy.** Pregnant women are not candidates for research MRI studies. As with medications and other imaging procedures, it is considered prudent not to undergo MRI during pregnancy unless there is a medical need. If you are a woman of child-bearing age, we will ask you to confirm that you are not pregnant, nor likely to be pregnant, at the time of the study.
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To be added to the signature page of all consents:

I also consent to have the data collected from this study entered in an anonymized manner, that is, without information that could identify me as the subject, in a research database that is shared by other investigators. The purpose is to compare with data from patients with several conditions and with those of healthy controls of the same sex and age.