*This sample is for researchers to use as a guide in developing their study materials. Instructions to the researchers are written* *in* ***[square brackets in bold italics]*** *and should be deleted. Instructions that are* *in* ***[square brackets, bold italics, and are blue]*** *need to be replaced with details specific to the study and changed to* black, un-bolded, un-italicized*, and removed from square brackets before uploading the material to the research ethics application.****Please also delete this instructional paragraph.***

**\*\*Please review the Guide to Creating an Information Letter and Consent Form for additional details\*\***

**SAMPLE INFORMATION LETTER for Research Involving fMRI**

**Project Title: *[insert title]***

**Principal Investigator (or Faculty Supervisor): *[insert name, department, phone, University of Waterloo email address]***

**Student Investigator(s): *[insert names, department, University of Waterloo email address]***

This letter explains what the study is about, possible risks and benefits, and your rights as a research participant. You may print/save a copy for your records. If you do not understand something in the letter, please ask one of the investigators before consenting to participate.

**Study purpose:**

***[Give a brief description in lay language of the purpose of the study]***

**Procedures:**

If you agree to participate, you will have images collected of your brain while you perform various tasks: ***[outline the tasks in the sequence in which they will be done]***. You will have the task(s) explained to you by the Principal Investigator ***[insert name of principal investigator]*** and the scans will be collected by a Grand River Hospital (GRH) MRI technician. The entire session should take approximately ***[insert time]***.

**Participation steps:**

1. You will begin by filling out a checklist to confirm you are an eligible participant.
2. The procedure for the scanning session will be explained to you.
3. You will be given ear plugs to protect your ears from the noise of the magnet.
4. You will be asked to lie on your back on the well-padded bed of the MRI machine. A cylindrical coil will be slid into place. This coil does not touch any part of your head but will surround your head. Above this coil are goggles that you can look through (they are not worn like a pair of glasses would be but sit above your eyes without touching you at all). The goggles have LCD screens in them, and this is how we present visual stimuli to you in the magnet. You will be asked if you are comfortable at which point the GRH MRI technician will move you into the MRI machine.
5. You will have multiple scans (these are called ‘runs’), each lasting approximately 5 to 7 minutes. Between runs you are not required to do anything and will be able to relax. The time between runs is usually around 1 to 2 minutes. During each run you will be asked to keep your head still. To help you do this, we will pack foam or shape-able material around your head.
6. During the scan you will be asked to ***[describe whatever task/procedure participants will be requested to do during the study – e.g., pressing a button in response to some visual stimulus]***.
7. At the end of the runs described above (i.e., the scanning runs during which you perform the experimental tasks), an additional scan will be taken of the anatomy of your brain. This scan is needed so that we can overlap your brain activity from the functional scans onto an image of your own unique brain anatomy.

The whole procedure, including setup time, should take approximately ***[insert time here]***. Approximately ***[provide a number]*** participants will be included in this study.

**MRI details:**

You will be placed in an MRI machine which uses the same hardware and software that is used in MRI for patients. The MRI scans being collected here are designed to address research questions, and not to examine your brain for any medical reasons. MRI is a non-invasive technique which does not involve x-rays or radiation. This magnet has a field strength of 1.5 Tesla, which is the standard field strength used in most hospital settings. It is also the lowest field strength used for fMRI (i.e., many magnets now use 3 Tesla or higher). There are no known side-effects or complications that have occurred during or following functional MRI examinations.

The most important safety concern with MRI is to avoid having *any metal in your body or near the scanner*. Thus, it is very important that you carefully complete the checklist included with this form and alert the investigators if you have any concerns.

**MRI risks and discomforts:**

The MRI scan is not associated with any known risks to your health and there is no evidence that there will be either short-term or long-term side effects. However, if you are a woman of child-bearing age, it is important that you not be pregnant at the time of the MRI scan. Prior to the MRI you will complete a questionnaire designed to identify any reasons why you cannot participate in the study. You **may not** participate if you have:

1) an implanted cardiac pacemaker.

2) any metal implants, pieces of shrapnel, aneurysm clips, or wires in your head.

3) a history of seizures.

4) known claustrophobia.

You will hear moderately loud knocking or beeping sounds during the scan when the MRI machine is in operation. You will be provided with earplugs to dull the noise and to protect your hearing. Although you may find this noise to be unsettling, the machine cannot hurt you in any way. If you wish to stop the study at any time, or feel you need a break, please advise the researcher (who will be able to hear you through a microphone) or by pressing the experimenter call button. If you have any questions about participation, please feel free to ask the researchers and MRI technicians at any time.

During the scanning session you will be in voice contact with the operator of the MRI. You may ask the MRI technician to terminate the scan at any time. You will also be given a button press device that you can use to communicate your desire to terminate the experiment to the operator in the control room. You may do this at any time. You should terminate the experiment if you feel tired, claustrophobic or for any reason, prefer not to continue.

**Incidental findings:**

Use of the MRI scan in this research is designed to answer research questions, not to examine your brain medically. This MRI scan collected in this research project is not a substitute for one that a doctor would order, and it may not show problems that would normally be detected by a medical MRI scan. In addition, the researchers conducting this study are not qualified in the same way a radiologist is, to detect abnormalities on MRI scans. However, in the unlikely event that we do note an atypical finding on your anatomical MRI scan, we will be certain to inform you of our findings and suggest that you arrange a medical follow-up to interpret the significance of the findings, if any. We will also ask a radiologist, or other health professional, to look at your scan, and by signing this consent form, you agree to release the scan for this type of review. Since we are not trained to read MRI scans for clinical purposes, we might occasionally think something is abnormal that is, in fact, perfectly normal. We do not want to worry you with such false alarms. Therefore, if anything is seen on your scan that we are unsure of, we may, without informing you at the time, ask a radiologist, or other health professional, to look at your scan. By signing this consent you are giving us permission to do so. If no problem is found by the radiologist, you will not be told that this review step has occurred. If the radiologist cannot confirm that your scan is normal, then we will contact you and suggest that you arrange a follow-up with your general physician.

**Voluntary participation:**

Your participation is entirely voluntary. If you wish to stop at any time, or feel you need a break, please advise the researcher. You may also withdraw from the study by advising the researcher. If you have any questions about participation, please feel free to ask the researchers. If you wish to withdraw your study data after participating, please contact the researchers. You can request your data be removed from the study up until ***[insert date]*** as it is not possible to withdraw your data once papers and publications have been submitted to publishers.

**Confidentiality and security of data:**

Everyone’s results are confidential. Neither your identity nor any personal information will be available to anyone other than the investigators. Your identity is considered completely confidential; indeed, your name will not be included or in any other way associated with the data collected in the study.

Furthermore, because the interest of this study is in the average neural responses (i.e., the changes in brain activity from one task to the next) of the entire group of participants, you will not be identified individually in any way in any written reports from this research. Data will be kept for a maximum period of ***[insert time period]*** to which only researchers associated with this study have access.

***[If data may be shared in an online repository, please see the ICL guide for details about what information and language to include]****.*

**Benefits:**

Participation in this study will not provide any personal benefits, but it will provide you with an opportunity to learn about research in psychology in general and the topic of this study. The information obtained from the study may benefit society in general by giving a better understanding of ***[give a brief description of the benefits relative to the study at hand]***. If you are interested, we would be happy to provide you with the results of the study when it has been completed, which may take some years. Contact the researchers should you wish to receive a copy of the final report on the study when it becomes available.

**Remuneration: *[Please see the ICL guide for details and language to include for different types of remuneration e.g., for draws, pro-rating, etc.]***

You will receive $***[insert amount]*** in appreciation of your time commitment and to cover any travel costs for participation. You will also receive a detailed feedback sheet about the study. If you withdraw from the study the amount of remuneration will be prorated based on the time you spent in the study (i.e., if you spend half an hour in an hour-long study you will receive half of the amount stated).

**Ethics Clearance:**

This study has been reviewed and received ethics clearance through a University of Waterloo Research Ethics Board (REB ***[####] [Replace#### with the file number that is listed at the top of your ethics application]***). If you have questions for the Board, contact the Office of Research Ethics, toll-free at 1-833-643-2379 (Canada and USA), 1-519-888-4440, or reb@uwaterloo.ca. Furthermore, as the study is being carried out at ***[insert name of hospital/clinic]*** the study has also been reviewed by and received clearance through the ***[insert name of Research Ethics Board]***. You may also contact the ***[insert name of Research Ethics Board]*** office at ***[insert telephone number and email]***.

**Questions:**

For all other questions, please call ***[give researcher name and contact details including telephone number and Waterloo email]***.

***[Please check that all relevant study details are included, changes are made to the document to accurately describe the study and procedures, and delete the instructional text printed in bold italics before submitting to the Office of Research Ethics for review.]***