**CONSENT TO PARTICIPATE IN HUMAN MRI RESEARCH[[1]](#footnote-1)**

You are invited to participate in a research study by [list of investigators], from the departments of [list departments here] at The Hong Kong Polytechnic University. You have been asked to participate in this study because [list the reason]. Your participation in this study is entirely voluntary. You should read the information below, and ask questions about anything you do not understand, before deciding whether or not to participate.

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

**Purpose of Study:** [insert purpose of study]

**Procedures:**

If you agree to undergo an MRI, the amount of time you spend on the entire MRI procedure will be [insert duration]. The amount of time you spend in the MRI device will be [insert duration]. You will be asked to have a series of MRI pictures taken of your [insert name of body part such as the head]. These pictures are made with an MRI device that uses radio waves and a large magnet to create the images. The MRI pictures will be made while you lie on a narrow bed placed inside of a large magnet. Your understanding and approval of these procedures are required if you are to participate in this study. During the MRI scan, you may be asked to perform various tasks. Depending on the specific needs of the experiment, these include:

* [List tasks here]

During parts of the scan, you will be asked to remain very still for periods of up to 30 minutes (though most procedures will be much shorter).

All of the following may be part of your exam, depending on the specific requirements of the research:

* You may be asked to complete a brief questionnaire that will require two to three minutes of your time. You have the right to refuse to answer any question that you do not wish to answer.
* You may be asked to answer questions about your medical history. In addition, the investigators may perform a brief medical evaluation of your health status, as well as a brief standard physical neurological exam. The results will be used only in connection with the MRI procedure, and will not become part of your medical records.
* Electrical activity in your brain or eyes may be monitored during the study. This involves attaching small electrodes (EEG) to your skin or scalp. The electrodes are attached with a paste that can be removed easily using shampoo and water.
* During the procedure your eye movements may be monitored with a device specifically designed for this purpose. This device works at a distance from the eye itself and does not involve any direct contact with or injury to your eyes.
* The physiological signal (ECG, SpO2, EMG, and ETCO2) may be monitored by electrodes attached to your body. The electrodes will be attached with a paste that can be removed easily using soap and water. The procedure of attaching the electrodes generally takes two to three minutes.

**Benefits:**

You may receive no direct medical benefit from participating in this study. [State the benefits to subject and/or society.]

**Potential Risks and Discomforts:**

Magnetic Resonance Imaging (MRI) uses a powerful magnet to take pictures of your body. Because the MRI machine exposes the body to a very strong magnetic force, you will have to follow certain safety precautions to make sure there are no metal objects in or on your body. Before you undergo the MRI scan, MR personnel will ask whether your body contains any metallic medical devices or equipment, including heart pacemakers, metal prostheses, implants or surgical clips. You also will be asked whether you have had any prior injuries from shrapnel or grinding metal, and if your eyes have been exposed to metal particles.

If you have no metallic objects or particles in your body, you will need to remove all metal objects, including jewellery, watches, hair holders, or eyeglasses before entering the scanner room. You will need to empty your pockets of all materials, including keys, wallets, and magnetic cards such as ATM and credit cards. In addition, you will need to change into a patient gown. Finally, you may be asked to remove any eye shadow you may be wearing, because eye shadow sometimes contains metallic substances.

During the MRI examination, you will lie on a table that slides into a horizontal tube slightly wider than your body. You will be asked to lie still, but you will be able to hear and speak to the MRI personnel/research staff. Some individuals experience anxiety, panic, or a sensation of claustrophobia when lying in the MRI machine. If you think this may happen to you, please tell the MRI personnel before the scan. The scanner also makes loud noises during its operation. You will be provided with ear protection to reduce the noise level. If you feel uncomfortable for any reason before or during the procedure, please tell the MRI personnel. If for any reason during the procedure you want to stop, you may do so by pressing the squeeze ball.

There are devices which will be used in addition to the MRI scanner such as button response boxes or equipment that monitors your physiological processes. These devices or the wires attached to them may generate a low level of heat. If you feel an uncomfortable heating/burning sensation, you should let the staff know immediately.

Although there is no evidence that participation in an MRI examination by a pregnant woman would be harmful to her foetus, a woman who is pregnant, or who thinks that she might be pregnant, should refrain from participating in the examination.

No studies have reported significant risks associated with the levels of the MR that you will be exposed to in the MRI examination. However, you should be aware that there could still be other risks which are unknown to researchers in this field.

**Participant Responsibilities:**

As a participant of a research study, your responsibilities include:

* Follow the instructions of the radiographer, MR personnel, and/or research staff.
* Inform the radiographer, MR personnel and/or research staff about any side effects, doctor visits, or hospitalizations that you may have.
* Inform the radiographer, MR personnel and/or research staff if you believe you might be pregnant.
* Inform the radiographer, MR personnel and/or research staff if you have some type of implanted electrical device (such as a cardiac pacemaker). You will not be allowed to participate in this study if you have one.
* Ask questions as you think of them.
* Inform the radiographer, MR personnel and/or research staff if you change your mind about staying in the study.
* Inform the radiographer, MR personnel and/or research staff if you are taking part in any other research project(s). This is to protect you from possible undesirable procedures or events such as extra blood drawing, extra x-rays, interaction(s) of research drugs, or other hazards.

**Possible Discovery of Medical Findings:**

When an MRI examination is performed, MR personnel may find something unexpected in the images. ***Since you are participating in a research project, the research team will not conduct a diagnostic review of the images and hence no written or verbal report of the results of the MRI examination, normal or otherwise, will be issued.***

**The MRI Examination Does Not Substitute a Clinical Examination:**

The MRI examination that you will receive is part of a research study. The researchers and The Hong Kong Polytechnic University do not bear responsibility for identifying or failing to identify abnormalities in the scan images. However, you may choose to be informed (or not to be informed) about incidental findings (if any) in the consent form. With this consent, the researchers may inform you when abnormalities are detected in your scan images. In no case will the MRI examination that you will undergo replace a visit to your own doctor. The images generated from the MRI examination will not be released to you for personal use.

**Privacy and Confidentiality:**

The only personnel who know that you are a research participant are members of the research team. No information about you, or provided by you during this research, will be disclosed to others without your written permission, except:

* if necessary to protect your rights or welfare (for example, if you are injured and need emergency care); or
* if required by law.

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity.

**Consent:**

I, , have received an explanation of the details of this study. I voluntarily consent to participate in this study. I understand that I can withdraw from this study at any time without giving reasons, and my withdrawal will not lead to any punishment or prejudice against me. I am aware of any potential risk in joining this study. I also understand that my personal information will not be disclosed to people who are not related to this study and my name or photograph will not appear on any publications resulting from this study. I affirm that I do not have a cardiac/heart pacemaker, brain aneurysm clips, any implanted metallic or electrical device, or any internal metal foreign object(s).

If there is any incidental finding, I:

* wish to be informed by the principal investigator (PI)
* do **NOT** wish to be informed.

I can contact one of the investigators, [name of contact person] at [phone number of contact person], about this study. If I have complaints related to the investigator(s), I can contact [name and contact of person in charge of complaint in your department]. I know I will be given a signed copy of this consent form.

**By signing this form, I willingly agree to participate in the research it describes.**

**Please note that the MRI examination does not substitute a clinical examination.**

Name of participant: Signature: f

Name of parent or guardian: Signature: 2

 *if applicable if applicable*

Name of researcher: Signature: d

 Date: 1

1. Not applicable to projects with contrast agent injection. [↑](#footnote-ref-1)