HONG KONG BAPTIST UNIVERSITY

**INFORMED CONSENT STATEMENT**

**Project title**

You are invited to participate in a research study on the neuroscience of XXX. Participation in this MRI study is completely voluntary. You have the right to stop anytime and terminate the procedures without any negative consequences.

**Procedures**

When you arrive at the scanning facility, you will fill out some paperwork, including a consent form and an MRI pre-screening form. We ask that you arrive a few minutes early to fill out the paperwork. After the paperwork is filled out, you will change into a hospital gown. This makes sure that any metal on your clothing does not affect the scanner. Lockers with locks are provided to store your possessions while you are in the scanner.

While you lie on a narrow bed placed inside a hollow tunnel of a powerful magnet, MRI images of your brain are produced by utilizing radio waves and the magnet. During the MRI scanning process, you are required to keep very still for periods of up to 30 minutes and may be instructed to perform various tasks.

For the MRI section, we will give you headphones that block out the scanner noise and play the sounds you will listen to. We will keep your head secured using foam pads and a headrest. Because you have to lie very still for a while, we will make sure you are as comfortable as possible when you get into the scanner. You will get a cushion beneath your knees and a sheet to keep you from getting chilly. In the one hand, you will hold a squeeze-ball that allows you to communicate with the researchers during the scanning session. In the other hand, you may hold response buttons. If you need to get in contact with them, you can ***squeeze the squeeze-ball***, and they will stop the scanner and talk to you. There is a small mirror in front of your eyes that will allow you to see the pictures projected on a screen behind the scanner.

After you are in the scanner, you will be asked to do some tasks similar to what you have practiced. This task will ask you XXX. This part will usually last 30 minutes. Then the scanner will take high-resolution anatomical pictures of your brain. This part lasts for about 30 minutes. After your scan is complete, we will take you out of the scanner, and you may change back into your regular clothes. You will receive cash compensation at the end of your scanning session.

**RISKS**

Since MRI makes use of strong magnetic field generated by a large magnet to produce pictures of your body, magnetic force of attraction can be as large as resulting in injuries if you have unsuitable metallic objects inside or on your body. In addition, the radio waves used in MRI may significantly generate heat in your body and even lead to thermal burns because of inapproriate clothings worn and positioning. Hence, you are required to follow the safety precautions to minimize the above risks.

Before proceeding to the MRI scan, you will be interviewed by a trained MR personnel and be asked regarding the following: 1. any metallic medical devices or equipment, including but not limited to heart pacemakers, metal prostheses, implants or surgical clips. 2. any previous injuries from shrapnel or grinding metal, 3. eye injury by metallic objects and 4. any known foreign body in your body and eye 5. now or used to be metal worker.

If you do not have any metallic objects within your body, you will be asked to get changed to a patient gown and to remove all metal objects, including but not limited to body piercings, jewelry, watches, hair holders, eye spectacles and coloured contact lens. In addition, you will be asked to clear your pockets of all materials, including keys, wallets, and magnetic cards such as ATM and credit cards. Finally, before entering the scan room, you may be asked to remove any eye makeup which may contain metallic substances.

During the MRI examination, you will need to lie on a bed that slides into a hollow and narrow tunnel. Some individuals may become uncomfortable, panic, or even experience shortness of breath owing to a sensation of claustrophobia in such confined area of space. If you think that you are likely with the above signs, please tell the MRI personnel before the scan.

During the scanning process, the equipment will generate loud noises as it operates. You will be provided with ear protection to reduce the noise level. If you feel uncomfortable with the noise issue, please tell the MRI personnel at any time during the procedure.

Although MRI is a safe and noninvasive method for looking inside the body, you should not participate in a research MRI scan if: You have any metal implanted in your body, such as: a piercing that cannot be removed; a permanent retainer; a cochlear implant; a pacemaker; an aneurysm clip or other surgically implanted metal replacement joints; screws from a broken bone; You are pregnant or trying to become pregnant; You have worked with metal, such as welding, or if there may be metal flakes in your eye; You are claustrophobic or afraid of spending a long time in a closed space (such as inside the scanner).

**EMERGENCY MEDICAL TREATMENT**

In the unlikely event of physical injury resulting from your participation in this research, emergency medical treatment will be provided at no cost to you. Be certain that you immediately notify the researcher if you are injured. If you require additional medical treatment you will be responsible for the cost. No other compensation will be provided if you are injured in this research.

**BENEFITS**

Incidental medical findings may arise in the images produced in MRI examination. You should understand that due to research nature of this study, no diagnostic report of the results based on MRI images (not limited to written or verbal format), normal or otherwise, will be issued. In addition, the MRI scan you receive in this study is **not** asubstitute for a clinical examination.The researchers and Hong Kong Baptist University shall not bear responsibility for identifying or failing to identify abnormalities in the scan images.

**CONFIDENTIALITY**

Participants will be given a random ID. No records identifying the subject will be maintained. The research data will be kept for up to 7 years only upon completion of the project.

**COMPENSATION AND INSURANCE**

For participating in this study you will receive \_HK$200 in cash. If you withdraw from the study prior to its completion, you will receive \_\_$100\_.

**CONTACT**

If you have questions at any time about the study or the procedures, you may contact the researcher, Dr. Rongjun YU, at rongjunyu@hkbu.edu.hk , and 34117581.

**CONSENT**

I have read and understand the above information. I have received a copy of this form. I agree to participate in this study.

Signature of the Subject \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of the Parent/Guardian (if needed)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of the Experimenter\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**香港浸會大學** **研究同意書**

**XXXX**

您被邀請參加一項關於XXXX神經科學研究。 參與這項 MRI 研究是完全自願的。 您有權隨時停止和終止程序而不會產生任何負面後果。

**程序**

當您到達掃描設施時，您將填寫一些文件，包括同意書和 MRI 預篩查表。 我們要求您提前幾分鐘到達以填寫文件。 填寫完文件後，您將換上醫院的病號服。 這可確保衣服上的任何金屬不會影響掃描儀。 當您在掃描儀中時，提供帶鎖的儲物櫃來存放您的物品。

當您躺在一張狹窄的床上時，該床位於一個由強大磁鐵構成的空心隧道內，您大腦的 MRI 圖像是利用無線電波和磁鐵生成的。 在 MRI 掃描過程中，您需要在長達 60 分鐘的時間內保持靜止，並且可能會被指示執行各種任務。

對於 MRI 部分，我們將為您提供耳機，以阻擋掃描儀噪音並播放您將聽到的聲音。 我們將使用泡沫墊和頭枕固定您的頭部。 由於您必須安靜地躺一會兒，我們將確保您在進入掃描儀時盡可能感到舒適。 您將在膝蓋下方放一個墊子和一條床單以防止著涼。 一方面，您將握住一個擠壓球，以便您在掃描過程中與研究人員進行交流。 另一方面，您可以按住響應按鈕。 如果您需要與他們聯繫，您可以擠壓擠壓球，他們會停止掃描儀並與您交談。 您眼前有一面小鏡子，可以讓您看到掃描儀後面屏幕上投影的圖片。

進入掃描儀後，系統會要求您執行一些與您練習過的類似的任務。 XXXX。 這部分通常會持續 XXXX 分鐘。 然後掃描儀將拍攝您大腦的高分辨率解剖圖片。 這部分持續約XXXX分鐘。 掃描完成後，我們會將您帶出掃描儀，您可以換回平時的衣服。 掃描結束後您將獲得現金補償。

**風險**

磁力共振掃描過程中所使用的強磁場會對特定金屬物質形成強大吸力。如您體內有此類金屬物質所製造的植入物，進入強磁場環境可能會對您造成嚴重傷害。再者，掃描使用到的無線電波可能會在您身體累積大量熱能，甚或可能因不適合的衣著或身體姿勢而造成燙傷 。故此，您需遵守下列安全守則以減低以上提及的風險。

在進行掃描前，研究人員會詢問您 1.體內金屬製醫療儀器，包括但不限於心臟起搏器、金屬假肢、金屬支架或手術夾 2.曾被鋒利金屬或金屬顆粒傷害 3.眼睛曾被金屬物件傷害以及 4.已知的體內金屬異物 5.曾否從事五金行業。

如您體內並未有上述病史，您將需換上檢查服，並暫時移除身上的金屬物，包括但不限於身體部位穿環、首飾、手錶、髮箍、眼鏡或有色隱形眼鏡。另外，你將需清空衣服口袋裡的所有物件，包括但不限於鑰匙、錢包以及磁卡（例如提款卡及信用卡）。進入掃描室前，您將需卸下眼影，因眼影可能包含金屬成分。

在掃描過程期間，您平躺於窄長的掃描床上，床滑動至超強磁鐵內的狹窄通道中以啟動掃描。個別受檢者或會因身處幽閉空間而感到緊張焦慮、恐懼甚至難以正常呼吸。如您認為自己曾經或可能會出現上述情況，請立即通知研究人員。 另外，儀器在掃描期間會產生噪音，研究人員將為您提供特製降噪耳機以及即棄耳塞，以降低噪音至國際聽覺保護標準。如您在掃描前或中對噪音感到不適，請告知研究人員。

**緊急醫療**

萬一您因參與本研究而造成身體傷害，我們將免費為您提供緊急醫療治療。 如果您受傷，請務必立即通知研究人員。 如果您需要額外的醫療，您將承擔費用。 如果您在本研究中受傷，將不提供任何其他補償。

**好處**

MRI 檢查產生的圖像中可能會出現偶然的醫學發現。 您應該理解，由於本研究的研究性質，將不會出具基於 MRI 圖像（不限於書面或口頭形式）的結果診斷報告，無論是否正常。 此外，您在本研究中接受的 MRI 掃描不能替代臨床檢查。 研究者和香港浸會大學不對識別或未能識別掃描圖像的異常承擔責任。

**保密**

參與者將獲得一個隨機 ID。 不會保留任何識別主題的記錄。 研究數據僅在項目完成後最多保留 7 年。

**報酬**

參加本研究，您將獲得 \_HK$200 現金。 如果您在研究完成之前退出，您將收到 \_\_$100\_。

**聯繫**

如果您隨時對研究或程序有疑問，可以聯繫研究員余榮軍博士，電子郵件：rongjunyu@hkbu.edu.hk，電話：34117581。

**知情同意**

我已閱讀並理解以上信息。 我已收到此表格的副本。 我同意參加這項研究

被試簽名\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 日期 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

家長監護人簽名 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 日期 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

實驗者簽名\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 日期 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_