# HONG KONG BAPTIST UNIVERSITY

# **LIFE SCIENCE IMAGING CENTRE**

# MRI UNIT SAFETY MANUAL

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# 1. Facilities

Life Science Imaging Centre (LSIC) at The Hong Kong Baptist University (BU) proudly introduces a research-dedicated whole-body 3.0T Siemens Prisma MRI scanner, which is expected to serve as a major research infrastructure or central research facility to promote individual and collaborative research on transdisciplinary neuroscience studies.

The scanner is equipped with:

- high gradient performance (maximum gradient amplitude of 80 mT/m @ slew rate of 200 T/m/s simultaneously, on all three orthogonal axes) with an ultra-high-performance cooling system and force-compensated design for reduced vibrations;
- fully dynamic parallel transmit with TimTX TrueShape
- Tim 4G RF system with 48, 64, or 128 independent channels for faster imaging and higher SNR
- Tim 4G coil technology

Other related accessories include:

- Four 64-channel EGI sets and one MRI compatible EGI.
- MagPro X100+MO, MagVenture for TMS
- Eyelink 1000 plus (MRI compatible) for eyetracking

The scanner shall only be used for research, and the research subjects shall be volunteers only. The scanner shall not be used for clinical tests (excluding clinical research).

#### 2. Contact Information

Life Science Imaging Centre, Room G03A, G/F., Jockey Club Academic Community Centre, the School of Continuing Education (SCE) Tower, 9 Baptist University Road, Kowloon Tong, Hong Kong

浸會大學道9號 香港浸會大學 陳瑞槐夫人胡尹桂女士持續教育大樓

賽馬會師生活動中心地下 G03A 室 生命科學成像中心

**Open Hours:** 

Regular hours: Monday - Friday 9:00 - 18:00,

from 6PM to 10PM, demand-based;

Saturdays, Sundays and Public Holidays - pending on demand,

For booking request of use of MRI facility, please contact us via lsic\_enquiry@hkbu.edu.hk. LSIC staff will respond within 7 days after receiving request.

Fax Number: 3411 5058

#### 3. Site Access and Restrictions

#### 3.1 Safety Zones

With reference to ACR manual on MR safety, the MRI facility is divided into four safety zones as annotated on the floorplan (Figure 1). Four zones are labelled Zone I to IV, and each zone is progressively more restrictive.

# Zone I: Public Area

This area is freely accessible to the general public with no supervision required.

#### Zone II: MRI patient screening and preparation area

Subjects must pass the screening interview of MR safety and medical history with guidance of MR radiographer/other approved MR operators and get changed in this area. In addition, subjects

must be physically screened for presence of ferromagnetic materials before entering the restricted area.

For subjects with MR unsafe wheelchairs or walking aids, transfer of subjects to MR safe/conditional appliances must be performed in this area. The unsafe appliances should be kept in this area, with labelling clearing differentiating them from safe ones.

Subjects and other non-MR personnel must be accompanied by MR personnel. MR personnel are those who have passed MR safety training to ensure their safety and that of others working within Zones III and IV, including secondary users, primary users, the radiographers, and LSIC staff in charge of the MRI.

# Zone III: MRI Control Room and Equipment Room

Access is restricted to MR personnel and post-screened subjects/non-MR personnel only, where non-MR personnel must be accompanied by a MR personnel. For MRI examination involving human subjects, at least two MR personnel must be present in Zone III to facilitate expeditious responses to emergencies.

An AED is available in G/F guard room of Jockey Club Academic Community Centre. For details of location, please refer to section 14. A first aid kit are available in the control room. Please note that the AED and the first aid kit are not MR-safe. No components may be brought into the scanner room.

#### **Zone IV: Scanner Room**

Zone IV refers to the scanner room with the highest risk of potential hazards. This area binds to the same screening and education prerequisites as in Zone III.

Any subject or non-MR personnel entering Zone IV must be escorted by the radiographer/approved MR operators. Unapproved devices or objects are strictly prohibited for access into Zone IV.

The entrance to Zone IV is clearly marked with a prominently displayed illuminated sign stating "The Magnet is Always On"



Figure 1. Floor layout of MRI facility

# 3.2 Card Access

Access to the G/F MRI unit through both backdoor and main entrance requires a card key access, which is granted upon completion of safety training and passing MRI safety screening (Annex 1). Such access is authorized by LSIC staff and only to trained MR personnel with valid accreditation of training record.

To minimize risk of possible hazards of projectile accidents and damage to subjects, emergency door in the control room must always be closed except emergency condition.

# 4. Definition and responsibilities of different personnel

MR personnel are referred to individuals who have been successfully educated regarding MR safety issues through the process as mentioned in the designated pathway and at a level sufficient to ensure that they do not pose danger to themselves or others in the MR environment. Only MR personnel can enter Zone III or IV alone.

Such MR safety educational participation is repeated annually and documented as a record of continuous MR safety educational effort.

#### 4.1 MR personnel

#### MR director (Equivalent to MR research director (MRRD) in ACR guideline)

MR director is responsible for (1) ensuring the safe execution of the MR examination on all human subjects through maintaining appropriate and up-to-date safe practice guidelines, (2) always ensuring his/her accessibility to the MR operators during which the MR facility is accessible, (3) ensuring appropriate MR safety and quality assurance programs are implemented, and (4) handling reports of all adverse events, including MR safety incidents that occur in the MR facility.

#### MR executive director (Equivalent to MR safety officer (MRSO) in ACR guideline)

He/she is responsible for (1) ensuring accessibility to MR operators at all times that the MR facility is accessible, (2) ensuring enforcement of appropriate MR safety procedures, work instructions, emergency procedures, and operating instructions (3) managing hazards posed by the MR equipment, and monitoring the measures taken to protect against such hazards, and (4) maintaining records of the personnel who have been educated up to the safety requirements.

#### Radiographer

He/she is responsible for (1) ensuring that all access of Zone III and IV bind to local rule (2) scanning subjects, (3) providing user training and assessment (4) implementing routine scan protocols, and (4) optimizing image quality through conducting regular calibrations and quality assurance.

#### **Primary user**

He/she is qualified to independently operate the MRI scanner with minimal supervision. He/she ought to take responsibility for the safety of the subject and MRI system throughout the entire MR scanning process.

#### Secondary user

He/she is qualified to assist the primary user/radiographer in (1) subject screening, (2) preparing scans and (3) operating the MRI scanner. Exact responsibilities are subject to job allocation assigned by the primary user/radiographer.

#### 4.2 Non-MR personnel

#### **General Workers**

Security Guards, sanitation workers/janitors, air-conditioning/electric service workers, and other non-academic/non-LSIC staff who have not received MR safety training.

#### 4.3 Visitors

Subjects, companions and visitors.

# 5. MRI Safety Training Procedure

<u>Prior MRRD approval MUST be obtained for operating the MR scanner.</u> The following training pathway describes how a non-MR personnel could be trained to become secondary user (for detailed job explanation, view section 4), and more advanced, to serve as a primary user (for detailed job explanation, view section 4).

To become a MR personnel, please contact us via lsic\_enquiry@hkbu.edu.hk. LSIC staff will provide training details via email within 7 days after receiving the application.

To become a secondary user, you must contact LSIC staff to complete the following:

Step 1.1: Watch an ISMRM MRI safety video

Step 1.2: Attend MRI safety tutorial and system operation training organized by LSIC.

Step 1.3: Pass the practical MRI safety knowledge quiz and complete the MRI safety screening form (Annex 1).

Step 1.4: Familiarize and be competent with emergency procedures at the MRI facility.

Step 1.5: Attend the MRI lab tour.

Step 1.6: Be approved as secondary user by the MRRD.

To further become a primary user, you must complete the following:

Step 2.0: Obtain valid CPR+ AED certificate.

Step 2.1: Become a secondary user.

Step 2.2. Watch an Advanced MR safety video and pass the MR safety knowledge test. Step 2.3: Join on-site MR operation training.

Step 2.4: Assist a radiographer for at least 20 hours in subject screening, scan preparation, and operating the MRI system.

Step 2.5: Set up and perform at least 5 scan sessions with human subjects supervised by a radiographer.

Step 2.6: Complete a practical evaluation assessment, which requires independent completion of one entire scanning session of human subject, observed by radiographer.

Step 2.7: Be approved as a primary user by the MRRD.

Annual renewal of qualification is required to ensure that MR personnel are consistently equipped with adequate safety knowledge to handle their duties in MR environment.

# 6. MR Safety Screening

6.1 Subjects and companions (for subjects requiring extra care, see section 13)

During initial subject recruitment, subjects are required to fill out a preliminary safety screening questionnaire. Researchers should inform subjects that history of eye injury by metal, metallic fragments/ implants, history of surgery or tattooing less than 6 weeks or implanted electronic device will not be allowed to undergo scanning. In addition, orthodontic braces produce significant artifacts and degrade the outcome image for examinations involving head and neck region. It is advised that the potential subjects with dental implants should be excluded from the study.

After preliminary screening, upon arrival on site, the subject and companion (for subjects requiring extra care) must complete verbal safety screening interview performed by primary user/radiographer in Zone II and sign the safety screening form (Annex 1).

Upon any doubt of medical history or compatibility of medical device or implant, access is always denied and MRRD always reserves the right of final decision.

Post-screened individuals are then required to remove all accessories (including but not limited to piercings, necklaces, hairclips, hairbands with metallic strips, watches, keys), eye makeups, hearing aids, wigs, removable dentures/ bridges, electronic devices, key cards with magnetic strips, belts. Subjects are further required to get changed to scanning gown. MR personnel should double check subjects with the ferromagnetic screening detector.

Equipment/ device entering MR scanning room must obtain prior approval of MRSO or radiographer. The approved equipment or device must be carefully labelled, signed and dated by the approver.

# 6.2 Contraindications

(1) Eye/body injury by metal,

(2) Metallic implants/fragments, for certain types of implants such as orthopedic screws/pins, cardiac stents, device name, model number with manufacturer name and date of implantation must be provided for verification of MR compatibility. LSIC reserves the right of final decision.

(3) Implanted electronic devices (include but not limited to pacemaker, insulin pump, deep brain stimulator) and its residual parts

(4) Pregnant subjects will not be scanned under any circumstances. Pregnant women (including visitors, companions etc.) are refrained from entering the scanning room.

(5) Surgery/ tattooing within 6 weeks. Subjects with (1) glow-in-the-dark tattoos, (2) tattoos with reflective metallic appearance (3) facial (including tattooed permanent makeup/microblading), scalp and genital tattoos are denied from scanning under all circumstances.

(6) Now or used to be a metal worker

(7) Cochlear implant

(8) Body weight > 250 kg (550 lbs) (maximum weight allowed for imaging table in Siemens' Manual)

Important Note:

- (1) To facilitate better and reasonable use of MRI facility, researchers are advised to perform preliminary screening based on the preliminary screening questionnaire and in cases with implants, an official proof letter of implant details with the following information must be obtained to consult advice from MRSO/ radiographer at least 7 days before enrolling subject in the study.
  - a. Referring physician name and signature
  - b. Subject name and identification document number
  - c. Implant name
  - d. Manufacturer name
  - e. Model number
  - f. Any official supporting document suggesting the MR compatibility of the device in 3T environment (optional but this can facilitate the verification process)

Note: LSIC reserves right of final decision for admission of implants into scanning room.

(2) In cases where doubt arises on the reliability of declaration of medical history made by subjects and/or compatibility of implants/device, LSIC reserves the right to deny the subject from scanning process.

# 6.3 A checklist of safety and screening procedures

- I. Before enrolling subjects
  - 1. Principal investigator applies for use of MRI through sending email of express of interest to lsic\_enquiry@hkbu.edu.hk
  - 2. If research team would like to introduce any special equipment during scanning, principal investigator must state clearly together in the application:
    - a. name of equipment
    - b. manufacturer name
    - c. model number
    - d. serial number of equipment and

e. any official supporting document suggesting the MR compatibility of the device in 3T environment

Note: LSIC reserves right of final decision for admission of special equipment into scanning room.

- 3. Research team brings the equipment with model and serial number SAME as the one stated in application to the MRI facility;
- 4. Radiographer and MRSO verify the equipment compatibility and adhere the dated MR conditional label on the equipment.
- 5. At least one member of research team must enroll in the MRI training and follow the training process of becoming a secondary user;
- 6. If research team wishes to use specific MRI scanning protocol (possibly available from documented literature), the principal investigator must state in the application together with the literature which has clearly described the details of scanning parameters. Additional consultation session may be required for feasibility of adopting and incorporating the specific protocol for the scanner;
- 7. Principal investigator/ appropriate delegate has to make appointment of scanning session at least 7 Days before on the online booking platform/system.
- II. Enrolling subjects

- 2. Researchers exclude subjects with contraindications from study;
- 3. In cases with implants, an official proof letter of implant details with the following information must be obtained to consult advice from MRSO/ radiographer at least 7 days before enrolling subject in the study.
  - a. Referring physician name and signature
  - b. Subject name and identification document number
  - c. Implant name
  - d. Manufacturer name
  - e. Model number
  - f. Any official supporting document suggesting the MR compatibility of the device in 3T environment (optional, but this can facilitate the verification process)
- 4. When researchers approach subjects for appointment, recommend them to wear garments (especially underclothing) entirely made of cotton/ polyester.
- III. Before arrival of subjects
  - 1. Researchers must confirm all their equipment to be used in the study are available in the list of existing equipment in LSIC or have already been verified and labelled as MR conditional/ safe by LSIC radiographer/ MRRD;
  - 2. Research team members who are secondary user or above have to set up the equipment for prior calibration;
  - 3. Research team member must ensure that subjects are legally capable of signing forms. If not, researchers must remind their legal guardian must accompany the subject and request him/her to complete the preliminary safety screening questionnaire as well;
  - 4. Primary user/ radiographer positions the coils to be used for scanning.

IV. Arrival of subjects

- 1. Researchers greet subjects and companion at the reception, explain the objective of their investigation and ask subjects/companion (for subjects requiring extra care) to sign informed consent form;
- 2. Researchers measure and record subjects' body weight and height using electronic balance available in the reception;
- 3. MR personnel bring subjects and companions (only for diminished cognitive/ communicative disorder/ claustrophobic subjects, must be legal guardians) to preparation room. For capable subjects, their companions can stay at reception only.
- 4. MR personnel performs verbal MR safety screening interview for subjects and companions (for subjects requiring extra care) in Zone II;
- 5. MR personnel explains to subjects that they will experience increase in body temperature and remind them if they are sweating, they have to inform the staff

immediately by pressing the squeeze bulb (to avoid risk of thermal burn) and acoustic noise produced by the scanner. Reassure them that subjects are carefully monitored via video monitoring and intercom. In addition, they will be given a squeeze bulb for requesting communication with staff during the scanning process;

- 6. Exclude subjects with contraindications/ any doubts on medical history;
- 7. Subjects and/or companion sign the MR safety screening form;
- 8. Radiographer/ Primary user verifies and confirms the screening information with subject;
- 9. Safety trained researcher bring subjects and companions (for subjects requiring extra care, must be legal guardians) to get changed and remove all accessories;
- 10. MR personnel performs final safety check on subject and companions using ferromagnetic detector. (IMPORTANT: NEVER use ferromagnetic detector on unscreened individuals as it may damage unknown implants of the individual);
- 11. MR personnel brings subjects/companions into scanning room.
- V. In the scanning room
  - 1. MR personnel ask subject to lie on imaging couch and explain the use of squeeze bulb to subjects and their right of termination of examination at any time should they experience discomfort despite measures taken (see section of claustrophobia);
  - 2. MR personnel provide headphone AND disposable earplugs to subject and companion for hearing protection;
  - 3. MR personnel connect the equipment and position the subject. Arrange the companion (for subjects requiring extra care/ claustrophobic subjects) to sit at proximity to the subject;
  - 4. MR personnel leave scanning room and initiate scan at the control panel.

#### VI. During scanning

1. MR personnel carefully monitor the condition of subject and companion through video monitoring, supervision camera and intercom throughout the scanning process.

#### VII. After scanning

- 1. MR personnel release the subject and companion to leave scanning room;
- 2. MR personnel disinfect the scanning table with alcohol swab;
- 3. Researchers arrange exit debriefing to subject and companion.

#### 6.4 Staff (MR Personnel) Screening

All MR Personnel have to complete an MR screening form (Annex 1) reviewed annually as part of their employment agreement to ensure their safety in the MR environment. When subject to any trauma, procedure, or surgery which involves possibility of introduction of ferromagnetic object or device into body, all MR Personnel must immediately report to the MRRD and this will enable appropriate screening of the employee to determine the safety of permitting that employee into Zones III and/or IV.

# 6.5 Staff (non-MR Personnel) Screening

Follow the screening procedures for subject screening.

# 6.6 Informed Consent

In addition to safety screening form, subjects are required to sign an informed consent (Annex 2), declaring that they have understood the procedures and possible risks of the examination. For subjects requiring extra care, their legal guardian(s) are required to sign on behalf of the subjects. In cases where subjects require interpreters for communication, both subject and interpreter are required to co-sign the consent form. Note that LSIC shall not be responsible for any cost of hiring an interpreter.

# 7. MR-related hazards and precautionary measures

#### 7.1 Static magnetic field

There are two sources of hazards related to static magnetic fields.

# 7.1.1 Rotational force (torque)

Rotational force occurs when an elongated ferromagnetic object is placed in a strong magnetic field and the magnitude of the force is proportional to the magnetic field strength. Therefore, maximum torque is expected to occur with uniform magnetic field with maximum magnetic field strength, therefore at the isocenter.

# 7.1.2 Spatial Field gradient (SFG)

Spatial Field gradient (SFG) refers to the variance in the temporally fixed static magnetic field surrounding the MR scanner and is described as change of magnetic field as a function of position around the MR scanner. Active or passive shielding of magnet results in rapid drop-off of strong magnetic field strength with distance from magnet, giving rise to steep spatial field gradient.

SFG give rise to following issues:

#### 1. Translational forces

Translational force occurs upon presence of SFG and increases with magnitude of the gradient. Maximum translational force occurs in the region with maximal SFG, therefore near magnet poles (entry of magnet bore).

#### 2. Lenz forces

Faraday's Law states that a changing magnetic field will induce a voltage and subsequent current in a perpendicular oriented electrical conductor. Lenz's Law further extends the theory and states that the induced current further generates a magnetic field opposing the original magnetic field, thereby attempting to stop the motion. Therefore, when an electrical conductor (including nonferromagnetic metallic objects) moves through the SFG, current generated within the conductor is directly proportional to the regional SFG value and rate of motion. Such current would further induce a secondary magnetic field which attempts to stop the primary motion.

Therefore, to move a MR conditional non-ferromagnetic device/equipment in scanner, it is advised to move slowly to minimize the opposing Lenz force.

#### 7.1.3 Projectile (missile) effect

When a strongly ferromagnetic object is introduced in MR scanning room, translational force and rotational force owing to strong static magnetic field can instantly accelerate the object which will become highly dangerous projectiles. In July 2001, a 6-year-old patient died of massive head trauma due to projectile event of a non-MR compatible fire extinguisher introduced into the scanning room.

Other potentially dangerous projectiles include wheelchairs, stretchers etc.

Another harmful effect caused by these two forces could be dislodgement of Ferromagnetic Implants from implanted position. For implants which are weakly ferromagnetic upon formal testing process, a waiting period of several weeks is advised by ACR to enable fibrous scarring to form and help anchor implant against weak magnetic force arising in MR environment. LSIC requests a minimum of six-week "waiting" period for the purpose.

#### 7.1.4 Bioeffects of static field

Upon exposure in strong static magnetic field, transient sensory disturbances can take place such as magnetophosphenes (generation of visual light flashes upon eye motion), metallic taste upon tongue motion.

Other short-term sensory effects such as dizziness and nausea have been reported. To mitigate the effects, individuals are suggested to move slowly around the scanner or at the scanner bore to minimize dB/dt in the fringe field.

#### 7.2 Time-varying gradient magnetic field

Gradients are formed by sets of electromagnets in walls of MR scanner. During image acquisition, gradients are rapidly switched on and off with slew rate as high as 200 T/m/s.

Echo-planar imaging sequence, which is used in fMRI image acquisition, particularly utilizes rapid switching of frequency and phase gradients to obtain gradient echo. High rate of change of flow of current in the gradient coils can pose safety concerns for imaging, namely acoustic noise (owing to mechanical vibration of gradient system), peripheral nerve stimulation (induced voltage in nerve to rapidly switching field and heating effect on implants.

Acoustic noise generated by certain sequences (e.g. diffusion-weighted, EPI) can be as high as 110-130 dB. As required by The International Electrotechnical Commission (IEC), ear protection should be achieved to reduce exposure levels in MRI to below 99 dB. Hence, individuals in scanning room are necessary to wear earplugs (reduce by 29dB as stated by vendor 3M) AND headphones (reduce noise by 13dB as stated by manufacturer) during scanner operation to screen off noise for protection.

Peripheral nerve stimulation refers to the depolarization of nerves caused by rapid switching of gradient. Such stimulation is not dangerous but requires it to be limited to avoid pain and even cardiac events theoretically.

The heating effect of implant by varying gradient field is due to internal eddy current generated within the implant with indirectly heat to surrounding tissue. When compared with heating effect by RF field, the magnitude of gradient heating effect is much less significant.

#### 7.3 Radio-frequency (RF) fields

#### 7.3.1 Diffuse Heating effect

RF pulse is applied to excite the precessing protons in tissue to produce MR signal. Thermal effect arises owing to energy dissipation of co-existent electric field to tissue via resistive heating by induced ionic currents and dielectric heating by vibration of polar water molecules.

Such energy deposition in tissue by RF irradiation per unit mass is measured in terms of specific absorption rate (SAR), measured in W/kg.

According to international standard of safety of MR equipment issued by International Electrotechnical Commission (IEC) and US Food and Drug Administration (FDA) IEC 60601-2-33, whole body and head SAR should not exceed 4W/kg and 3.2W/kg respectively at the level of first level controlled mode (<=8.0T) with environmental temperature less than or equal to 25 degree Celsius.

Sequences with fast (turbo) spin echo, inversion recovery (e.g. STIR,FLAIR), saturation pulse (e.g. fat saturation, spectral saturation), gradient echo sequences with very short TRs (e.g. bSSFP, TOF MRA) are prone to have high SAR which may result in hyperthermia in organs.

Extra care has to be taken for patients susceptible to overheating, including but not limited to infants, obese, diabetics, febrile patients and the ones with cardiac decompensation.

# 7.3.2 Heating effect of conductive metal in bore

For MR conditional equipment placed in bore, excessive RF power accumulated in the equipment may cause thermal injury to the subject or individuals. Therefore, large loops of conductive metal should be avoided through:

Ensuring that the wires are straight, remove any loop or knot alongside and avoid crossing of multiple wires.

Ensuring that wires are running in parallel to the static magnetic field across the bore.

Separating wires which serve for different purposes, e.g. ECG, EEG.

Keep wires at sufficient distance to subject skin or use padding like blanket to separate wires from subject.

# 7.3.3 Proximity burn

Thermal injury/burn can occur when subjects' skin is in touch with RF transmit coil. To prevent such event from happening, adequate padding meeting manufacturer's specification should be placed between subjects' skin and coil. In addition, large induced current loops can be created within subjects' own tissue with points of skin-to-skin contact, such as both thighs. Insulation pads should be placed in between to cut such conducting loop formation. In addition, MR personnel must remind subjects to avoid putting hands on hips and avoid crossing arms and/or legs to prevent creating conducting loops.

# 7.3.4 Tattoos

Metal ink is commonly used to create tattoos and therefore brings about the risk of thermal burns.

Tattoos within 6 weeks, tattoos with glow-in-the-dark or reflective metallic appearance are contraindicated from scanning. Tattoos over 6 weeks are not necessarily contraindicated. Yet subjects with tattoos have to be informed of possible heating effect and notify the staff immediately in case of discomfort felt at the tattoo site.

# 8. Ground rules of using MR facility

All individuals

- 1. No food or beverages, or tobacco products can be consumed or used.
- 2. Smoking is strictly prohibited.
- 3. To avoid allergic reactions from taking place, scented products are not allowed to be used, including but not limited to perfume, hair spray, aromatherapy, aftershave and cologne)

#### MR personnel

- 1. Pregnant MR personnel may enter the scanning room for positioning subjects, but are not allowed to remain in the examination room while scanning.
- 2. Before entering scanning room, make sure that you have removed all the accessories (including but not limited to pigmented contact lens, piercings, necklaces, hairclips, hairbands with metallic strips, watches, keys), eye makeups, hearing aids, wigs, removable dentures/ bridges, electronic devices, key cards with magnetic strips, belts.
- 3. While scanning, always ensure that there are at least 2 MR personnel present in the unit in case of any emergencies.
- 4. Always keep the scanning room door CLOSED unless admitting and dismissing subject.
- 5. Disinfection of the headphones and imaging couch should be done after usage.
- 6. Return the used coils and equipment to their designated positions after use.
- 7. Handle all costly coils and equipment with care.

#### Subjects and companions

1. You are highly recommended to wear underclothing entirely made of cotton or linen. If not, you will need to remove it when getting changed.

2. If you experience discomfort/ sweating during scanning process, you are required to press the squeeze bulb and communicate with our staff through the intercom

#### 9.Use of gadolinium contrast/sedation

Injectable contrast agents and sedation/anaesthesia are not permitted in LSIC.

#### **10.Exam attire**

It is mandatory for all subjects to get changed to gown provided by LSIC. Please note that all underclothing, unless entirely made of cotton or linen, may pose threat to thermal burns.

The following clothings are prohibited for scanning:

- 1. Garments with "anti-microbial", "anti-odor", "heat retaining" function. Invisibly fine metallic fibers are commonly incorporated in these garments;
- 2. Athletic/ workout clothing, including but not limited to sports bra, sports underwear and compression wear;
- 3. Clothing made of zicron fabric;
- 4. Damp and wet.

Upon notice of scanning appointment, researchers should recommend subjects to wear underclothing entirely made of cotton or linen. Otherwise, they would need to remove the underclothing when getting changed.

#### 11.Surveillance and Communication with subjects

Video monitoring

A wall-mounted video camera is available for monitoring the patient during an MR examination and displaying the information on LCD monitor in the control room.

#### Supervision Camera

Another video camera enables comprehensive monitoring of the subject's face irrespective of subject position during scanning. MR personnel are able to detect signs of discomfort and anxiety immediately and promptly respond to subjects' need.

Squeeze bulb

If the subject feels discomfort or needs assistance during scanning, he/she can set an alarm through pressing squeezing the bulb to alert the MRI personnel. When positioning a subject for scanning, MR personnel will give a squeeze bulb for subject and provide him/her instruction of usage.

Intercom

MR personnel can give instructions and sooth subjects in between sequences. In addition, after pressing squeeze bulb, subjects can discuss with MR personnel regarding region of discomfort and whether to continue the scanning process.

# 12.Claustrophobia

MR personnel can take the following measures to ease anxiety of claustrophobic subjects before cessation of scanning.

- 1. Use of headphone which plays soothing music to reduce adverse impact of acoustic noise;
- 2. Turn on the light in the bore;
- 3. Apply reflecting mirror provided by manufacturer which can allow subject to see objects out of the bore;
- 4. Use of intercom to regularly communicate and monitor subject;
- 5. For examinations out of head and neck regions, feet first supine can be used instead of head first supine;
- 6. Ensure adequate ventilation in the bore;
- 7. Invite safety screened companion to accompany subject in scanning room;
- 8. Reassure subject that he/she can terminate the scanning at any time;
- 9. Use of "Quiet suite" mode which can reduce the sound pressure generated by coils.

#### 13.Subjects requiring extra care

Subjects requiring extra care are defined as follows:

- 1. Aged under 18;
- 2. Diminished cognitive capability;
- 3. Diminished communication capability/ deafness;
- 4. Visual impairment.

To ensure their safety during scanning process, it is necessary to take the following precautionary measures.

- 1. Safety screening of subject must be done with his/her companion (parent/ legal guardian) and counter-signature of companion is required on the completed safety screening form and informed consent form.
- 2. Safety screening of companion must be completed;
- 3. Companion must be able to accompany the subject in the scanning room to take care of the subject at all times of scanning. Failure to do so results in denial of access of subject.

# 14. Automated external defibrillator (AED) and first aid kits

The nearest AED available is at G/F guard room of Jockey Club Academic Community Centre. (Location of AED is shown in Figure 2)



In addition, a first aid kit is placed in the MR control room. Note that the AED and the first aid kits are MR unsafe and shall NEVER be brought into scanning room. In cases where resuscitation is required, always move the subject out of scanning room before using AED.

For MRI studies involving human subjects, there will be at least two MRI personnel present whenever a subject is in the scanner room. This policy is in place to facilitate expeditious responses to emergencies.

#### 15. Fire Extinguisher

The MRI control room has a readily accessible, clearly marked, MR-conditional fire extinguisher available. Additionally, there is a smoke detector system and a sprinkler system that will be automatically activated in case of smoke or fire respectively. The fire evacuation plan (Figure 3) is posted above the fire extinguisher and in the Safety Training presentation.



Figure 3. Fire Evacuation Plan of LSIC MRI unit

# 16. Emergency and Safety Training

ALL MRI personnel must take the up-to-date safety training and renew their user qualification annually. These individuals must also be fully aware of the current procedures for both medical emergencies and facility emergencies.

Emergency Situation and Procedures \*\*\* In case of a life-threatening emergency, please call 999 directly\*\*\*

Address of MRI facility:

Life Science Imaging Centre, Room G03A, G/F., Jockey Club Academic Community Centre, the School of Continuing Education (SCE) Tower, 9 Baptist University Road, Kowloon Tong, Hong Kong

# 浸會大學道9號 香港浸會大學 陳瑞槐夫人胡尹桂女士持續教育大樓

賽馬會師生活動中心地下 G03A 室 生命科學成像中心

Location of emergency buttons are summarized in Figure 4.



Figure 4. Annotated Summary of emergency buttons and equipment in MRI control and scan room

#### **16.1 Fire Emergency**

Definition: Fire or equipment failure such as sparking wires or signs of smoke in the MRI unit

#### **During working hour**

MR personnel should take the following steps:

- 1. Stop all scanning.
- 2. Press the **Emergency Electrical Shut-down switch** immediately (see Figure 6 and section 16.5).
- 3. Remove the subject from the scanner and lead the subject out to a safe area.

- 4. Activate the fire alarm by breaking the fire break glass to initiate a building evacuation.
- 5. MR personnel use MR conditional fire extinguisher (with clear writing of MR conditional on the body of the extinguisher) to extinguish the fire (only if safe). If the fire is uncontrollable, MR personnel may perform manual quench of magnet (follow Emergency Quench Procedure). NEVER BRING A STANDARD RED FIRE EXTINGUISHER FROM ELSEWHERE IN THE BUILDING INTO THE SCANNER ROOM.
- 6. CLOSE THE DOOR OF THE SCANNER ROOM.
- 7. Guide and evacuate subject to leave the building by the nearest fire escape route. Use stairs and do not take the lift.
- 8. After reaching a safe place, call the Campus Control Centre (CCC 24-hour Emergency Tel. No.: 3411 7777 or Ext. 7777 on the PABX system) for immediate assistance.
- 9. Wait for Emergency Medical Services to arrive.
- 10. If the fire department is called, wait for them to arrive so that they can take appropriate actions immediately. MR personnel must remind the firefighters of the presence of the magnetic field and warn them not to enter the MRI scanner room with non-MR compatible equipment.

# Out of working hour

Sign: The fire alarm rings and fire control surveillance panel indicating that there is fire/smoke inside the scanning room.

- 1. Security guard and technical worker arrive at the control room (the scanning room door is always closed and locked in non-office hours).
- 2. Check the CCTV and look through RF window to see if there is fire or smoke in the scanning room.
- 3.1. If there is fire/smoke:

3.1.1 Notify the fire department (must emphasize that the fire is in the MRI scanning room and there is a strong magnetic field) and Siemens for emergency assistance (Siemens customer service hotline: 2870-7500).

3.1.2 Perform emergency electrical shut-down (see Figure 6 and section 16.5).

3.1.3 The firefighter evaluates the situation at the control room through CCTV and RF window, and if deemed necessary, perform emergency quenching (see section 16.3).

The strong static magnetic field may not dissipate at once in case of incomplete quench.

3.1.4. Siemens engineer arrives and radiographer/ primary user performs safety screening procedures. If radiographer/primary user is not available, siemens engineer is required to sign a self-declaration form (Annex 3) on MR safety screening **BEFORE** entering the scan room.

3.1.5. If there is no radiographer or primary user on-site, ALL personnel (including all emergency personnel) must not enter the scanning room area until siemens engineer confirms that the magnetic field has completely dissipated.

# 3.2. If there is no fire/smoke:

3.2.1 If there is no radiographer/primary user on site, all personnel (including all emergency personnel) must not enter the scanning room area.

3.2.2 Radiographer/primary user performs MR safety screening to technical worker and confirms that technical worker is wearing appropriate clothing (shoes without metal) and removes metal items from the body, such as earrings, jewelry, watches, hairpins, glasses, or colored contact lenses. In addition, all items in the clothes' pockets, such as keys, wallets, and magnetic cards, are required to be emptied.

3.2.3 Technical worker brings MR compatible ladder and toolbox and enters the scanning room to check if the fire alarm is a false alarm.

3.2.4 After confirming that it is a false alarm, radiographer restores the facility and informs security upon complete restoration.

3.2.5 Before arrival of radiographer/primary user, if there is any change in room condition (smoke or fire), follow the steps for fire emergencies.

# **16.2 Medical Emergency**

In case of a medical emergency:

1. Stop all scanning.

2. Remove the subject from the scanner room to the waiting area for treatment.

3. CLOSE THE SCANNER ROOM DOOR.

4. Call 999 for the ambulance service if it is a life-threatening emergency.

5. Notify the 24-hour manned Campus Control Centre (CCC) at Tel. No. 3411 7777 and MR personnel for immediate assistance.

6. Radiographer/ primary user should provide immediate care to the subject. For minor injuries, please make use of the first aid kits, which are in a designated cabinet in the control room.

7. Wait for Security guards or paramedic (if 999 is called) to evaluate the incident and provide a professional first aid service. Do not let the injured person leave even if he/she feels better and never consider that assistance is no longer required.

8. Follow incident report guidelines and report to MRRD/ MRSO.

#### **16.3 Emergency Quench**

# During working hour, only MR personnel can quench the magnets in the event that the magnetic field itself poses an immediate risk to life or major property. Two such circumstances are:

Pinning of individual by non-removable ferrous object to magnet with life-threatening injuries
If there is a fire in the MRI scanner room that cannot be put out using a MR conditional fire extinguisher and requires the assistance of the fire department.

#### **Quench Procedure**

- 1. If possible, remove yourself and subject from scanner room before quenching the magnet.
- 2. Locate and press the QUENCH BUTTON in the control room or scanner room (Figure 4). (The quench button itself has the cross on magnet (Figure 5). Lift the plexiglass cover and press the button. This action is IRREVERSIBLE and has several consequences, e.g. cost 500k to fix the scanner.



Figure 5. Manual Quench button indicated by red square

- 3. When the magnet is quenched, the WARNING LED will light up and an alarm signal will sound. The helium in the scanner boils off. The magnetic field will fall to a safe level within 20 seconds.
- 4. The helium vent ducts become dangerously cold during a quench. Do not touch them.
- 5. If emergency medical assistance is needed, dial 999 and request medical assistance.

- 6. Immediately notify Siemens service (Siemens Customer Care Centre hotline: 2870-7500).
- 7. Police, fire, and other emergency personnel should be restricted from entering the scanner room with their axes, oxygen tanks, etc., until it can be confirmed by Siemens engineers that the magnetic field has dissipated.

NOTE: In the absence of a major emergency, users should NEVER quench the magnet.

#### **16.4 Spontaneous Quench**

The sudden appearance of white clouds or fog around or above the MRI scanner indicates that cryogenic gases have vented partially or completely in the scanner room.

1. If anyone is inside the scanner room while quenching occurs, MR personnel should OPEN the scanner room door immediately for ventilation. If you cannot open the door, press the emergency door release button.(see section 16.8)

2.MR personnel immediately evacuate all individuals from the scanner room.

3. Do not touch the helium ducts in the scanner room.

4. MRI personnel should perform **Emergency Electrical Shutdown procedure (See section 16.5)**.

5. There may also still be a considerable residual static magnetic field despite a quench or partial quench of the magnet.

6. Immediately notify siemens service for ad hoc service (Siemens Customer Care Centre hotline: 2870-7500)

7. Scanner room and control room access should be strictly restricted until the arrival of Siemens equipment service.

#### **16.5 Emergency Electrical Shutdown**

The following events should prompt an emergency electrical shutdown:

- 1. Smoke or fire coming from the scanner, equipment room or console.
- 2. Flooding has carried or is threatening to carry water into electrical equipment.

#### Electrical shutdowns do not turn off the magnetic field.

Procedure

1. Locate and press one of the large red electrical shutdown buttons (red with no writing on button) in the scanner room or control room (Figure 6). Make sure that it is the electrical shutdown button, NOT the quench button.



Figure 6. Emergency Electrical shutdown button

- 2. Electrical shutdown immediately stops all power to the scanner, the scanner equipment and the console computers. It does not turn off the lights. Also, power to the stimulation equipment will not be interrupted, so be aware that electrical or fire hazards may still be present.
- 3. In the case of fire or medical emergency, dial 999 for assistance.
- 4. Remove subject from the scanner room. Pull the "emergency release handle," (right side of the foot of the table if you are facing the scanner) (Figure 7 and 8)



Figure 7. Location of emergency release handle



Figure 8. Illustration of pulling the emergency release handle

5. Pull the bed out of the gantry manually using the handle at the foot of the table (Figure 9).



Figure 9. Illustration of manually pulling image table out of gantry

- 6. **DO NOT** quench the magnet unless there is a specific reason to do so.
- 7. Escort uninjured subject to leave. It will take at least a couple of hours to restore the scanner to operational status.

#### 16.6 Coolant Accidents (Frostbite)

Direct physical contact with sub-zero liquids, gases, and surfaces (e.g. pipes) may lead to frostbite. The eyes and mucous membranes are especially vulnerable. 1. If possible, move the injured individual to warm place

2.Call Campus Security (Tel.: 3411 7777) for assistance.

3. Call Community Emergency Service directly by dialing 999 if the situation is urgent or serious.

DO NOT conduct rescue operation unless you know for sure how to perform a proper rescue or you know the situation is safe.

4. Gently remove any constricting rings, gloves, boots or any other constricting items.

5.Accompany the injured individual to UHS/clinic. If emergency service is called, wait for emergency service for escorting the individual to the hospital.

#### **16.7 Power Outage Procedures**

1. If the power goes out while a subject is inside the scanner, pull the "emergency release handle," (right side of the foot of the table if you are facing the scanner) (Figure 7 and 8)

2. Pull the bed out of the gantry manually using the handle at the foot of the table (Figure 9).

#### 16.8 Scanner Room Door Failure

In the event of a power failure or a failure of the pneumatic system in the scanner room door, it may be necessary to press the emergency door open button which releases the pressure in the scanner room. Buttons are located in the scanner room (Figure 10) and in the control room (Figure 11).

You should never completely close the scanner door from the inside if no one is on the outside to provide assistance should this occur.



Figure 10. Emergency door release button in scanner room (indicated by red square)



Figure 11. Emergency door release button in control room (indicated by red square)

#### 17. Incident reporting

If encounter any adverse events, MR safety incidents, or "near incidents", all MRI personnel are responsible to immediately report to LSIC staff on the followings:

- 1. Time of discovering the event;
- 2. Type of event;
- 3. Any injury of personnel;
- 4. Any damage to equipment.

Upon receiving preliminary report from MR personnel, LSIC staff need to judge if further report to campus control office (CCC) is required. LSIC staff are required to report all adverse events to MRRD (Prof. Changsong Zhou, ext. 5089) or MRSO (Dr. Rongjun Yu, ext. 7581). For details, please refer to Hazardous Occurrence Reporting And Investigation Regulations (Annex 3) and fill in the Hazardous Occurrence Investigation Report.

A printed copy of this safety manual is available in the Prisma control room. You should familiarize yourself with its location.

Annex 1a: MRI safety screening form (English Version)

#### Hong Kong Baptist University Life Science Imaging Centre

#### MAGNETIC RESONANCE (MR) PROCEDURE SCREENING FORM

#### Section I. Project Information (to be completed by research assistant/fellow)

Exam Date	PI's Name	
Project Contact Person	Tel. No.	
Project No.	Subject No.	

#### Section II. Subject Information and Medical History (to be completed by subject)

Name				Gender	M / F
HKID/Passport No.				DOB (DD/MM/YY)	
Body height (m)				Body weight (kg)	
Please tick the followin	g appropriate boxes a	and spe	cify if ap	oplicable	
Description		Yes	No	If "Yes",	
				please specify time and	d details
1. Prior surgical operation	ations				
2. History of :					
a. Chronic Illness					
b. Brain Surgery					
c. Stroke					
d. Cancer					
e. Asthma					
f. Walking aid require	ed				
(stick/ wheelchair)					
3. Known/ Possibility	of pregnancy				
(female subjects o	nly)	First d	lay of L	ast Menstrual Period:	
					(DD/MM/YY)

Section III. Safety Questionnaire (to be completed by MR personnel, endorsed by subject, verified by radiographer/primary user)

Many objects (Including but not limited to implants and devices) are HAZARDOUS and UNSAFE in the MRI environment. Notably, these objects may be present in your body. To ensure your safety, please carefully indicate if you have or have had any of the following:

	Yes/Not Sure	No
1 Eye injury by metal		
2 Body Injury by Metallic Object		
3 Metallic foreign bodies (e.g. Bullet, Shrapnel, etc.)		

	Yes/Not Sure	
4 Now or used to be metal worker		
5 Aneurysm Clip		
6 Cardiac Pacemaker / Defibrillator		
7 Neurostimulator		
8 Electronic Device / Implant (e.g. Pill cam, Infusion Pump, etc.)		
9 Shunt		
10 Stent / Filter / Coil		
11 Cochlear (Middle Ear) Implant		
12 Hearing Aid		
13 Eye Implant / Eyelid Spring / Wire		
14 Metal Rod / Pin / Screw / Joint Replacement		
15 Prosthesis (e.g. Artificial Heart Valve, Eye, Limb, Penile, etc.)		
16 Breast Tissue Expander		
17 Glucose Monitoring Sensor / Medication Patch		
18 IUD / Contraceptive Diaphragm / Vaginal Pessary		
19 Surgery/ Tattoo within 6 weeks		
20 Tattoo / Permanent Makeup		
21 Denture / Dental Retainer / Dental Brace / Dental Implant		
22 Accessory / Body Piercing / Wig		
23 Cosmetic Colored Contact Lenses		
24 Claustrophobia		

WARNING: NEVER enter MRI restricted area if you hold any doubts or concerns regarding an implant, device, or object. ALWAYS consult our radiographers or system health lab research staff BEFORE entering the MRI scanning room. Please note that the MR SYSTEM MAGNET IS ALWAYS ON.

#### Section IV. Declaration

I confirm that the above information is correct to the best of my knowledge.

I have read and understand the contents of this form and had the opportunity to ask questions regarding the information on this form and regarding the MR procedure that I am about to undergo.

Subject/ Parent/ Guardian's Signature	MR personnel Signature	
Subject/ Parent/ Guardian's Name	MR personnel Name	
Relationship: Subject / Father/ Mother	Verified by	
/ Guardian	radiographer/primary user	
Date: (DD/MM/YY)	Date: (DD/MM/YY)	

Annex 1b. MRI safety screening form (Chinese Version)

#### 香港浸會大學生命科學成像中心

#### 磁力共振安全篩查問卷(研究受驗者用)

#### 第一部分. 研究項目詳情 (由研究助理填寫)

受驗日期	項目導師	
項目聯絡人	聯絡電話	
項目編號	受驗者編號	

#### 第二部分. 受驗者資訊(由受驗者填寫)

姓名			性別	男/女
香港身份證/			出生日期(日/月/年)	
身份證明文件號碼				
身高(米)			體重 (公斤)	
請仔細閱讀下列問題,並在相應空格加上	こレ及描	述詳情	(如適用)	
	有	無	如有,請列明時間及詳情	
1. 曾接受手術				
2. 已知病歷				
1、長期病患				
2、腦部手術				
3、中風				
4、癌症				
5、哮喘				
6、正在使用輔行工具				
(拐杖/輪椅/助行器)				
3. 現正/可能懷孕				
(60 歲或以下女性受驗者適用)	上次經	<b>密期首日</b>	:	(日/月/年)

#### 第三部分.磁場安全篩查(由研究助理填寫,受驗者確認,放射師/認可操作人員核實内容)

在高强度磁場下,許多物品(包括但不限於植入醫療裝置及儀器)並不安全,甚至可能會爲你帶來 危險。為保障你的安全,請仔細閱讀下列問題,如有任何以下病史,請列明詳情。

	有/不確定	無
1 眼眶內金屬異物		
2眼睛 / 身體曾被金屬利器所傷		
3 體内金屬異物(例如子彈、金屬碎片)		
4 現正 / 曾從事五金行業		

4 現正 / 曾從事五金行業	有/不確定	無
5 腦動脈瘤夾		
6 心臟起博器 / 除顫器		
7 神經刺激器		
8 體内電子植入裝置或儀器(例如: 膠囊內窺鏡, 輸液泵等)		
9 體內分流器		
10 支架 / 過濾器 / 線圈		
11人工耳蝸(中耳)		
12 助聽器		
13 眼部植入物 / 眼瞼彈簧 / 金屬線		
14 金屬棒 / 針 / 螺釘 / 關節置換物		
15 人工假體(例如:人工心臟瓣膜,眼球,義肢,陰莖等)		
16乳房組織擴張器		
17 血糖監測感測器 / 藥貼		
18 宮內節育器 / 子宮隔膜 / 子宮托		
19過去6個星期內曾接受手術/紋身		
20 紋身		
21 假牙 / 牙齒固定器 / 牙套 / 植牙		
22 飾物配件 / 體環 / 假髮		
23 有色隱形眼鏡		
24 幽閉恐懼症		

警告:如閣下對掃描過程有任何疑慮,必須在進入磁力共振掃描室之前咨詢放射師或研究人員。 請注意掃描室内,<u>高强度磁場一直存在。</u>

#### 第四部分. 聲明

我確認上述資訊全部屬實無訛。

我已仔細閱讀並理解問卷之全部內容及磁力共振掃描過程,並有充分機會就上述問卷及掃描内容 向研究人員作出提問。

受驗者本人/	研究助理簽署	
(18歲以下受驗者適用)受驗者直系家屬/監		
護人簽署		
受驗者姓名	研究助理姓名	
(18歲以下受驗者適用)受驗者直系家屬/監	放射師/	
護人姓名	認可操作人員姓名	
與受驗者關係: 受驗者本人/	放射師/	
受驗者直系家屬 (父/母)/	認可操作人員簽署	
受驗者監護人簽署		
日期(日/月/年)	日期(日/月/年)	

#### Annex 2a. Informed consent form template (English version)

#### HONG KONG BAPTIST UNIVERSITY INFORMED CONSENT STATEMENT

**Project title of** [the university which engages HKBU to perform the scan]

You are invited to participate in a research study conducted by [ ] on the neuroscience of XXX and are referred by [ ] to have a MRI scan at Hong Kong Baptist University. Participation in this MRI study is completely voluntary. You have the right to withdraw from participation anytime 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. Please arrive about [15] minutes early to fill out the paperwork. After the paperwork is filled out, you will be asked to get changed and wear a hospital gown. [All [ ] shall be removed. ] 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 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 As 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 practiseed. 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.

#### <u>RISKS</u>

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, 6. any other relevant question(s).

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**

You shall immediately notify the researcher [ ] if you are injured.

#### **BENEFITS**

Please note 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. The MRI scan you receive in this study is **not** a substitute for a clinical examination. You may\_contact [the university which engages HKBU to do the scan] for further details in relation to the nature of the research. [The MRI images will be sent to the [the university which engages HKBU to do the scan] direct. Please contact [the university which engages HKBU to do the scan] if you have any enquiry.

#### **CONFIDENTIALITY**

Participants will be given a random ID. No records identifying the participant 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 by [ ] you will receive [ ] directly from [ ].]\_

#### **CONTACT**

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

#### **CONSENT**

I have read and understand the above information, and agree to abide by the terms and conditions as set out in this form [and the Points to Note]. I have received a copy of this form. I agree to participate in this study subject to and in accordance with the terms and conditions as set out in the Points to Note. I understand that any non-compliance with the Points to Note may result in safety issues and I am aware of the risks associated therewith as set out in the Points to Note. I undertake to comply with the Points to Note and have been given the opportunity to raise questions if I am in doubt of the content thereof. I understand that my participation in the research is voluntary and I consent to participate in the research including the MRI scan at Hong Kong Baptist University.

Signature of the Subject	
Name in Block Letters _	

Date \_\_\_\_\_

Signature of the Parent/	Guardian (if needed)	
Name in Block Letters		

Date					
-					

Signature of the Experimenter\_\_\_\_\_ Name in Block Letters \_\_\_\_\_ Date \_\_\_\_\_

Annex 2b. Informed consent form template (Chinese version)

#### 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。

#### <u>程序</u>

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。

#### <u>風險</u>

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。

#### <u>緊急醫療</u>

#### 如果您受傷,請務必立即通知研究人員。

#### <u>好處</u>

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,您將從\_\_\_\_\_獲得現金\_\_\_\_。如果您在研究完成之前退出,您將從\_\_\_\_\_收到 \_\_\_\_\_。 <u>聯繫</u>

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:<u>rongjunyu@hkbu.edu.hk</u>,電話: 34117581。

#### <u>知情同意</u>

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

#### Annex 3a. Self-declaration form on MR safety screening for emergency use (English Version)

#### The Hong Kong Baptist University Life Science imaging Centre

#### Self-declaration form on Magnetic Resonance Safety Screening

This form applies only to the handling of **emergencies in non-office hours** (such as confirming the complete dissipation of magnetic field in scan room after emergency quench by siemens engineers) when the radiographer/primary user is not available on-site. Before entering the scan room, Siemens engineers must complete and sign this self-declaration which is witnessed and signed by a Baptist University staff.

#### Part 1. Self MR safety screening

#### WARNING: Please note that the MR SYSTEM MAGNET IS ALWAYS ON.

Many objects are HAZARDOUS and UNSAFE in the MRI environment. To ensure your safety, please carefully read the following statements and put tick in appropriate boxes.

I, (name)\_\_\_\_\_\_ (HKID number:\_\_\_\_\_\_) confirms that:

1.I have sufficient knowledge of MRI-related safety to work in a 3T magnetic field environment and understand the related hazards and risks.

2. I have removed all removable metal objects from my body, including but not limited to hairpins, jewelry, wallets, etc.

**3**. I do not have the following contraindications:

- Metallic medical devices in my body, including but not limited to pacemakers, metal prostheses, stents, or surgical clips (except those fulfilling 3.1)
- Injuries caused by metallic shrapnel or metal particles;
- Eye injuries caused by metallic objects;
- Known metallic foreign bodies/medical implants in my body;
- Surgery within the past six months;
- Currently or previously a metal worker;
- Currently or possibly pregnant AND

3.1. For any medical implants/ devices present in my body (if applicable), I confirm that they are well compatible in 3T MR environment;

4. The tools I am bringing into the scan room are compatible with 3T MR environment and do not pose any danger to anyone or any facility.

**5**. I understand and acknowledge that the Hong Kong Baptist University and Life Science Imaging Centre shall not be responsible for any form of injury, loss or legal liabilities which is caused my failure to comply with the above MR safety screening conditions.

#### Part 2. Self-Declaration

 $\Box$  I have read and understood the contents of this form and confirm that the above information is correct to the best of my knowledge.

Sign of Engineer	Witness Sign (見證人簽署)	
Name of Engineer	Witness Name (見證人姓名)	
	Witness HKBU staff number	
	(見證人職員號碼)	
Date (DD/MM/YY)	Date (DD/MM/YY) (日期)	

# Annex 3b. Self-declaration form on MR safety screening for emergency use (Chinese Version)

#### 香港浸會大學生命科學成像中心

#### 磁共振安全自我聲明書

此聲明只適用於<u>非辦公時間發生突發危急事故</u>(例如緊急移除磁場後確認掃描室磁場完全消失), 放射師 / 認可操作人員未能及時抵達現場情況下,西門子工程師在進入掃描室前必須先填妥此聲 明,並由 **浸大職員作見證人**簽署確認作實。

#### 第一部分.磁場安全自我篩查

#### 警告: 請注意掃描室内, 高强度磁場一直存在。

在高强度磁場下,許多物品(包括但不限於植入醫療裝置及儀器)並不安全,甚至可能會爲你帶來 危險。為保障你的安全,在作出聲明前,請仔細閱讀下列內容並謹慎回答,並在相應空格加上✔。

本人\_\_\_\_\_\_(身分證號碼:\_\_\_\_\_\_)確認:

□1.自己已經具備足夠的磁共振相關安全知識以應付 3T 磁場環境中工作,及了解相關風險;

□2.已移除所有身上可移除的金屬物(包括但不限於髮夾,體環,錢包等);

3.沒有以下禁忌症;

- 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 (如符合第3.1項除外);
- 曾被鋒利金屬或金屬顆粒傷害;
- 眼睛曾被金屬物件傷害;
- 已知的體內金屬異物/醫療儀器;
- 過去六個月內曾接受手術;
- 現正或曾經從事五金行業;
- 現正或可能懷孕。

及

3.1 我體內有植入式醫療儀器/裝置 (如適用),而我確認這些植入物/裝置是 3T 磁場相容的。↓↓4.確認進入掃描室所攜帶的工具在 3T 磁場相容,不會對任何人或設施構成任何危險。

#### └──J5.清楚明白<u>香港浸會大學及生命科學成像中心概不負責因本人未能配合或忽略以上磁場安全篩</u> 查條件所造成的任何形式上的損傷或損失,及其衍生的任何法律責任。

# 第二部分. 聲明

□本人已仔細閱讀並理解聲明之全部內容,並確認上述資訊全部屬實無訛。

工程師簽署		見證人簽署	
工程師姓名		見證人姓名	
		見證人職員號碼	
日期(日/月/年)		日期(日/月/年)	