

Safety Guidelines and
Code of Practice for Conducting
Magnetic Resonance Imaging (MRI)
Experiments Involving Human Subjects

Birkbeck/UCL Centre for Neuroimaging
26 Bedford Way

Version 18, 08 October 2024

Table of Contents

<u>INTRODUCTION.....</u>	<u>4</u>
<u>FACILITIES</u>	<u>4</u>
<u>PERSONNEL (AS OF 14TH FEBRUARY 2022)</u>	<u>5</u>
<u>LINE OF RESPONSIBILITY</u>	<u>5</u>
<u>ACCESS TO FACILITIES</u>	<u>5</u>
GENERAL.....	5
ACCESS FOR MAINTENANCE STAFF AND CLEANERS	6
VISITORS	6
<u>PRINCIPLES OF MR IMAGING.....</u>	<u>7</u>
<u>POTENTIAL RISKS.....</u>	<u>8</u>
EXPOSURE TO A STATIC MAGNETIC FIELD.....	8
SPECIFIC RISK MANAGEMENT FOR STATIC MAGNETIC FIELD.....	9
EXPOSURE TO THE RF FIELD	9
SPECIFIC RISK MANAGEMENT FOR RF ENERGY	10
EXPOSURE TO RAPIDLY SWITCHED MAGNETIC FIELDS.....	11
SPECIFIC RISK MANAGEMENT OF RAPIDLY SWITCHING MAGNETIC FIELDS.....	11
ACOUSTIC NOISE	11
SPECIFIC RISK MANAGEMENT OF ACOUSTIC NOISE.....	12
<u>DEMARCATIION OF FIELD LINES (5-GAUSS LINE).....</u>	<u>12</u>
<u>TRAINING AND CERTIFICATION.....</u>	<u>12</u>
CONSOLE OPERATOR TRAINING (LEADING TO CERTIFIED OPERATOR STATUS)	12
OPERATOR TRAINER (LEADING TO OPERATOR TRAINER STATUS)	13
USER SAFETY TRAINING (LEADING TO CERTIFIED USER STATUS)	13
<u>RISK MANAGEMENT OF PARTICIPANTS.....</u>	<u>14</u>

<u>SUBJECT POLICIES.....</u>	<u>16</u>
SUBJECT CONFIDENTIALITY	16
ETHICS AND CONSENT.....	16
NEUROLOGICAL ANOMALIES DISCOVERED IN THE COURSE OF SCANNING	17
<u>SCREENING</u>	<u>17</u>
<u>DEVICES</u>	<u>17</u>
<u>EMERGENCIES.....</u>	<u>18</u>
OXYGEN DEPLETION	18
FERROMAGNETIC OBJECTS	18
QUENCH	18
MEDICAL EMERGENCIES.....	19
FIRE.....	19
EMERGENCY EVACUATION	20
OPERATOR ILLNESS.....	20
<u>LONE WORKING</u>	<u>20</u>
<u>MANUALS.....</u>	<u>21</u>
<u>SIGNAGE.....</u>	<u>21</u>

Introduction

The purpose of this document is to define a set of safety standards and safety procedures for conducting magnetic resonance imaging (MRI) experiments involving human subjects at the joint Birkbeck/UCL MRI Centre. The manual briefly describes the Centre's facilities, including the imaging modalities available.

A brief description of the principles of MR imaging is provided as background to the risks associated with MR experiments. Subsequent sections are organised into topics in line with requirements that must be implemented before an investigator begins work at the Centre.

The requirements to be met before scanning include:

1. Obtaining approved review of the study protocol from the Centre Directors after a scheduled project presentation;
2. Establishing a PI account and subject-screening documentation via the BUCNI website; and
3. Providing the Centre with an ethics code and approved Informed Consent form from the relevant ethics committee (typically UCL PALS or UCL Bioethics committee).

Facilities

The Birkbeck/UCL Centre for NeuroImaging (henceforth BUCNI) is dedicated solely to research. It is not a medical facility.

BUCNI houses two scanners: 1) a Siemens Avanto 1.5 Tesla full-body MRI scanner, and 2) a Siemens Prisma 3T full-body scanner. Both scanners have multiple head and surface coils and a full complement of peripheral devices, some of which are described below.

BUCNI is located in the basement of the UCL Psychology Department, 26 Bedford Way London WC1, and also houses a reception area, changing and toilet facilities, and an equipment room.

Personnel (as of 14th February 2022)

Director	Fred Dick	f.dick@bbk.ac.uk, f.dick@ucl.ac.uk
Associate Director (<i>on leave from March 2022</i>)	Tessa Dekker	t.dekker@ucl.ac.uk
Ethics Chair	Essi Viding	e.viding@ucl.ac.uk
MR Physicist	Oliver Josephs	o.josephs@fil.ion.ucl.ac.uk
Technician & Physicist	Joerg Magerkurth	j.magerkurth@ucl.ac.uk
BUCNI Administrator	Winnie Yeh	w.yeh@bbk.ac.uk
Part-time Project Coordinator	Elisa Infanti	e.infanti@bbk.ac.uk
Fire Marshall	Joerg Magerkurth Fred Dick	
First Aid	Joerg Magerkurth	
Centre Safety Officer	Fred Dick	

Line of Responsibility

Everyone in the magnet suite has the responsibility to ensure safety.

The Centre-Certified Operator running the console has the ultimate responsibility for enforcing safety standards.

No one may cross into the magnet room without approval from the Centre-Certified Operator.

Access to Facilities

General

MRI Centre: Access is strictly controlled. During weekday working hours, key card access to the hallway leading to both scanners is automatic for UCL PALS staff and graduate students and for other BUCNI members with a UCL access card. (To obtain this clearance, please email Winnie Yeh). All others must be accompanied by Centre members.

At the entrance to the general reception area, there is a currently a videophone keypad. Any MRI Centre visitor is the responsibility of the person who let them in until the visitor leaves the area.

Console (control) rooms: ONLY safety trained personnel are to be given the digital door access code. All people entering the console room MUST BE SCREEN by an Operator using the pre-screen form that is posted on the BUCNI website; personal effects must be left in lockers in the changing facility or in the reception/waiting area.

No one may enter the console rooms unless they have been screened and checked for metal objects by a Centre-Certified Operator. If there is an experiment scheduled, this screening must be carried out by the Operator who is booked for the experiment.

Magnet rooms: Access is restricted to Centre Operators, Operator-accompanied participants, and Operator-accompanied, safety-trained individuals directly involved with the research study being conducted at the time of entry. THE OPERATOR HAS THE RIGHT AND RESPONSIBILITY TO ASK ANY PERSON TO LEAVE THE CONSOLE ROOM AT ANY TIME IF THEY FEEL THERE IS A SAFETY PROBLEM.

Access for maintenance staff and cleaners

Maintenance of the scanner is performed by Siemens and its subcontractors.

Maintenance of the chiller, compressor, and air conditioner units is performed by UCL Estates and its contractors. These companies will need to gain access by arrangement with the Centre Director. All must be screened if they need to enter the magnet room.

Cleaning: For their safety, and that of others, cleaners are not allowed in the equipment or magnet rooms unless specifically scheduled and approved by BUCNI staff. Trained named cleaners will clean the scanner suite (reception, console rooms) and on scheduled times and with documented training, will clean the scanner rooms with approved non-magnetic cleaning equipment.

Visitors

Visitors are not permitted in the magnet room without consent from the Centre Directors or physics staff (Josephs, Magerkurth), followed by a complete metal pre-screen immediately before going into the magnet room as with all other personnel and subjects.

Principles of MR Imaging

Magnetic resonance imaging (MRI) is a highly flexible technique for making images of the human body. Hydrogen nuclei (protons) behave like small magnets, so that when a subject lies in a magnet the protons tend to align with the magnetic field. When properly excited the protons precess (rotate), producing a measurable signal in a nearby detector coil. The frequency of precession is proportional to the local magnetic field, so by making the field vary across the body the signals arising from different locations can be distinguished based on their frequency. There are three basic components to an MRI system: 1) a large, static magnetic field (e.g., 1.5 Tesla); 2) radio frequency (RF) coils that are used as a transmitter to excite the MR signal, and as a receiver to detect the MR signal; and 3) gradient coils that are pulsed on and off to produce linear gradients of the magnetic field for imaging.

MRI techniques involve pulsing currents through the RF and gradient coils, so a particular technique is often referred to as a pulse sequence. By varying the pulse sequence, one can produce an enormous range of images with different spatial and temporal resolutions, and with substantially different contrast between tissues in the image.

Functional MRI (fMRI) is used to measure changes in blood oxygenation and blood flow that accompany neural activity. When a particular area of the brain is activated, the local blood flow increases dramatically and the local blood is more oxygenated. This change in oxygenation affects the local MR signal, so fMRI provides a way to map patterns of activation in the working human brain. In a typical fMRI experiment, rapid dynamic images are acquired while a subject alternates between experimental and control conditions. The time series of images is then processed on a voxel-by-voxel basis to identify voxels that show a significant correlation with the alternating experimental and control periods.

The main magnetic field is provided by a large magnet with a cylindrical bore; fixed within the bore is the gradient coil. A computer-controlled bed moves in and out of the magnet bore to position the subject's head at the midpoint of the gradient coil. For most brain imaging, the subject's head rests inside the head RF coil. For functional MRI studies, three types of imaging are used:

1. Localizer: Brief images (about 20 seconds each) are acquired in three orthogonal planes in order to identify structural landmarks and choose the locations for imaging in the rest of the experiment. Typical time required is 1 min, although if re-positioning of the participant is necessary additional localizers may be required.

2. High resolution anatomical images: A 3D imaging sequence is used to acquire images of the entire brain at high resolution (e.g. 1x1x1 mm). The pulse sequence typically used is a 3D gradient echo, usually with an inversion preparation, which typically requires 5-10 minutes.

3. Rapid dynamic imaging: Dynamic images are acquired while the subject performs the chosen task. Typically the pulse sequence used is an echo planar imaging (EPI) method with in-plane resolution of 2-3 mm, and a slice thickness of 2-3 mm. Typically each image is acquired after a single RF pulse, and the maximum image acquisition rate is about 12-15/sec. With multiband or 3D EPI sequences, this rate increases with the acceleration factor.

A full fMRI experimental session then consists of a localizer, one or more high-resolution anatomical scans, and typically 3-6 dynamic imaging runs. Total time for the session ranges from 45-120 minutes.

Potential Risks

An established hazard associated with MR imaging is that the magnet exerts a strong force on ferromagnetic objects. For this reason, ferromagnetic objects are excluded from the vicinity of the magnet so that they will not become projectiles. No pacemakers, metallic implants, neurostimulators, or loose metal objects are permitted inside the magnet room unless specifically authorized by the Centre Director in writing. Metal objects (e.g. limb braces, traction mechanisms, or stereotaxic devices, etc.) should not be placed within the MR magnet.

In addition, each subject undergoes a standard 2-part questionnaire-based screening procedure to determine whether they have any implanted materials that may pose a risk (see current checklist on BUCNI website). If there is any doubt about the nature of any implanted material, the subject may not be scanned. Although no other risks have been established for MRI, there are four areas of potential concern for which there are prudent limits:

Exposure to a static magnetic field

The FDA guideline is that magnetic fields up to and including 4 Tesla pose no significant risk. The limit of 4 Tesla is based not on known risks at higher field, but rather simply a lack of long-term data at those fields. Such higher field studies are underway at a few institutions. The Centre's 1.5T magnetic fields are within the guidelines provided by the United States Food and Drug Administration (FDA) and UK Health Protection Agency for clinical imaging and fall within the category of no significant risk. In high magnetic fields, rapid motion of the head can cause dizziness, vertigo, nausea, or a metallic taste. For this reason, the scanner bed moves slowly into the magnet bore

and the subject is encouraged to remain still while in the region of the static magnetic field. The Operator will ensure that rapid movements on the subject's part are minimized as the subject enters and exits the vicinity of the magnet. During the scanning, head motion is restrained by padding inserted between the subject's head and the head RF coil or other similar support.

Magnet sites often distinguish a Security Zone, defined by the magnet room and its walls, from an Exclusion Zone defined by the 5-Gauss line, which might extend beyond the magnet room. For the 1.5T scanner, the 5-Gauss (0.5mT) line is inside the magnet room so that the Security and Exclusion Zones are the same. For the 3T scanner, the Exclusion Zone extends into the console room and part of the adjacent office. People with pacemakers should not enter the Exclusion Zone.

To reduce electrical resistance, superconductive magnets use cryogenics to super-cool the electrical conductor that generates the static magnetic field. Temperatures of the cryogenics used can be as low as -269°C (-452°F). Very rarely, a sudden boil-off of all of the cryogen, called a quench, occurs. A quench is accompanied by a loud noise and causes the rapid loss of the magnetic field and may result in oxygen depletion within the magnet room. (See Emergencies)

Specific Risk Management for Static Magnetic Field

- All persons must be properly screened by a Centre-Certified Operator immediately before entering the magnet room
- All personnel must guard against the introduction of ferrous objects at all times
- Operators should discourage rapid movements within the scanner
- Operators must be knowledgeable about quench risks and procedures

Exposure to the RF field

The RF fields used in MRI are non-ionizing electromagnetic radiation, and so do not pose the same type of risks as x-rays and radioactive tracer techniques. However, the RF fields do cause tissue heating. The FDA guideline is that there is no significant risk if the specific absorption rate (SAR) is: a) Less than 4 W/kg whole body for 15 minutes; b) Less than 3 W/kg averaged over the head for 10 minutes; c) Less than 8 W/kg in any gram of tissue in the head or torso for 15 minutes; or d) Less than 12 W/kg in any gram of tissue in the extremities for 15 minutes. The pulse sequences used at the Centre are similar to standard clinical pulse sequences, with minor modifications, and the radio frequency energy loss in the tissues is well below these guidelines. In addition, the scanner software calculates the amount of heating expected during the scan and compares the estimate against predetermined levels. If the estimate exceeds the levels, the system adjusts scan parameters. The complete estimate of excessive heat

exposure is based on the subject's weight. Consequently each subject's weight must be accurately entered into the system before scanning. Inadvertently setting weight low can trip the power monitor below the SAR limit. Inadvertently setting weight high can reduce the maximum number of slices/images that can be acquired per unit time. There is a sensor inside the magnet's bore to monitor temperature. Incorrectly entering a person's weight will not expose the participant to excessive SAR, however, entering the correct weight is a critical step for managing RF energy risks.

It is important to note that RF- or gradient-switching-induced heating of metallic jewellery (rings, necklaces, earrings), underwire bras (including 'sports bras'), and other metallic objects (both ferrous and non-ferrous) may be sufficient to cause tissue burns. It is especially important to keep unused RF coils well away from the scanner table, as these have been responsible for first- to third-degree burns reported in the literature. Any metal forming a loop should not be near to the subject's skin. Current induction can also take place in other closed loops, including clasped hands; therefore, subjects must be instructed to keep their hands uncrossed, and monitored for hand position while in the scanner. Finally, current induction and heating may also occur with water or sweat. Thus the operator should assure that the subject is wearing clean and dry clothing, and that temperature and humidity in the scanner room is not fluctuating. (Alarms in the console room will sound if humidity and temperature move beyond acceptable limits).

Specific Risk Management for RF energy

- Each person's weight must be entered into the appropriate program field before starting a scanning session.
- Subjects should not be scanned if they have damp clothing, come in contact with the RF transmit coil surface, come into contact with a looped wire, or if unconnected receive coil or other cables have not been cleared from within the RF transmit coil.
- Use non-conducting pads when needed. Position the subject's hands to the side and ensure that legs are not crossed.
- Place foam between the subject and the bore.
- Excessive removable eye makeup should be removed prior to a scan.
- Subjects with permanent makeup may not be scanned without prior approval by the Centre Director.
- Extra vigilance is required when scanning subjects with tattoos due to the potential risk of skin irritation. Please consult the Centre Director for questions.
- Jewellery should be removed prior to a scan. On a case-by-case basis the Console Operator may decide whether rings may be worn during a scan.
- Head studies producing SAR values greater than 3.2 Watts/kg must be approved by the Centre Director in addition to having explicit Ethics approval.

Exposure to rapidly switched magnetic fields

The gradient coils used for imaging produce time-varying magnetic fields (slew rate in dB/dt). Such fields, if sufficiently strong, can produce peripheral nerve stimulation. Stimulation can occur in peripheral nerves, muscle, and blood vessels. The FDA guideline is that switched gradient fields pose a significant risk if dB/dt is sufficient to produce severe discomfort or painful stimulation. The mean pain nerve stimulation threshold, the level at which half of subjects are likely to report painful stimulation, is 90 Tesla/Second. The mean peripheral nerve stimulation threshold, the level at which 50% of subjects might report a tactile sensation or metallic taste is 60 Tesla/Second. The slew rate of a typical scan is 45 Tesla/Second. Gradient switching rates are limited in the pulse sequence software used for MRI to ensure that there is no discomfort for the subject.

Specific Risk Management of Rapidly Switching Magnetic Fields

- If the subject complains of pain or discomfort including headache stop the scan immediately. If the pain is not due to a biomechanical cause (awkward placement of body, poor placement of neck or head supports, etc.) terminate the study. If the discomfort is due to a biomechanical cause, the study may continue if the cause is corrected.
- If the participant complains of tingling, a light touch sensation, or muscle twitching stop the scan and assess the extent of discomfort. If the discomfort cannot be minimized, the study must terminate.
- Operators must report complaints of unexplained discomfort or pain to the Centre Director immediately after the subject has been removed from the scanner room.
- Scanner operators should make sure that each participant knows that s/he should alert the operator if discomfort arises during the scan.

Acoustic noise

When current is pulsed through a gradient coil sitting in a magnetic field it acts somewhat like a loudspeaker, creating a sharp tapping sound at the characteristic frequency of gradient pulsing (around 1 kHz). The sound levels are most intense during dynamic imaging that requires rapid gradient switching. Sound pressure levels at the centre of a head gradient coil were measured to be in a range from ~88 dB SPL for the Siemens Avanto 1.5T Scanner (Siemens documentation). UK legislation provides for protection for noise at or above 80dB. All subjects will wear ear protection, using either MRI-approved foam earplugs or ear defenders. Dispose of earplugs after each subject is scanned.

Specific Risk Management of Acoustic Noise

- During scanning, all those present in the scanner room must wear BUCNI approved ear protection. Currently these include: centre-provided earplugs, CONFON headphones, or Sensimetrics ear-buds in conjunction with external foam pads.
- Operators must monitor subjects to assure that they are comfortable with noise levels

Demarcation of field lines (5-gauss line)

Within the Avanto (1.5T) room, the 5-gauss line is marked around the magnet in red tape on the floor. In the Prisma scanner, the field extends around the entire exam room.

Training and Certification

Console Operator Training (leading to Certified Operator status)

Only individuals who have successfully gone through the Centre's training program may perform MR scanning. Centre Operator status is awarded following completion of BUCNI Operator Training. Operator status is maintained at the Directors' discretion and may be revoked at any time.

1. Operator trainees should have approximately 20 hours of hands on experience operating the scanner under the guidance of a BUCNI operator trainer. Operator trainers are the only people who can train new operators. They are listed on the BUCNI scheduler. IN ADDITION -

- a) The total number of hours required will be at the discretion of the instructor, and is also dependent on previous experience.
- b) Only one person can be being trained at a time because only one person can be operating the scanner at a time. So even if there are multiple experimenters present, only one is gaining training hours at a time. Observing is also beneficial, however, but it needs to be agreed with the PI of the study and with the operator running the session.
- c) The 20hrs should include scanning for at least 2 different studies to promote some minimal generalizability.

2. ScanOp trainees must receive some basic training in what to do if things go wrong, including
 - a) Manually getting the bed out
 - b) Dealing with incidental findings
 - c) Possible emergency situations (eg metal in the scan room, medical emergencies, fire, etc.) and how to deal with them

This will be covered in the Advanced Operator training session.

3. A separate document (Checklist for BUCNI Operator Training) summarizes the skills and knowledge that operators need to be able to demonstrate on completion of training.

4. Successful completion of BUCNI Operator Training involves attending the Advanced Operator Training session and demonstrating one's knowledge of the information and skills in the Checklist. Formal completion comes when the Trainer and Trainee sign off on the Checklist skills sheet and bring it to the Centre Administrator in BUCNI.

Graduates of the program receive a Centre-Certified Operator account on the BUCNI system. To maintain active certification an operator must regularly perform research scans at the Centre and attend regular safety training and operator refresher sessions. The Centre Director will monitor operator activity. During MRI research studies the Centre-Certified Operator has the on-site responsibility to implement the safety guidelines.

Operator trainer (leading to Operator trainer status)

To become an operator trainer, BUCNI provides additional, specific training for this role. Certified operators who want to be trained up as operator trainers need to meet with BUCNI project coordinator for an induction and familiarise themselves with the training material and Calpendo training progress documentation. Given the increased responsibility that comes with being an operator trainer, eligibility for the role of operator trainer will be determined at BUCNI's discretion.

User Safety Training (leading to Certified User status)

All staff and students involved in research at the MRI Centre must complete a safety training course BEFORE beginning work at the Centre. This course lasts about one hour and is composed of a safety lecture and a detailed walk through of the facility. Certified Centre User status is awarded at the Centre's discretion and may be revoked at any time.

ALL researchers must be certified as having successfully completed safety training for the joint UCL/Birkbeck scanner centre. Researchers who have completed an equivalent safety training course at another MRI facility, such as the UCL Functional Imaging Laboratory, Institute of Psychiatry, or Institute for Child Health are NOT exempt from this.

Risk Management of Participants

All studies conducted in the scanner will have to be approved in advance by the appropriate institutional (e.g., UCL, Imperial) or national (e.g. NHS) Ethics committee.

BUCNI certified personnel, i.e. certified operator and certified users, are trained to keep participants safe during scans, and each of these individuals is responsible for safety around the scanner, although the scanner operator has ultimate responsibility (see Line of Responsibility, p.5).

There are minimum requirements regarding the number of BUCNI certified personnel in attendance under different circumstances, depending on the participant group and time of scanning:

	Monday-Friday 9:00-1800	Outside normal working hours
Healthy adult participants	1 certified operator	1 certified operator + 1 additional safety-trained person
Children (16 and under) and healthy older participants (>65)	1 certified operator + 1 additional safety-trained person	1 certified operator + 1 BUCNI-approved safety-trained person
Special populations	1 certified operator + 1 additional safety-trained person	1 certified operator + 1 BUCNI-approved safety-trained person

Note that normal operating hours do not include Bank Holidays or other holidays where the University is not technically open. Scanning during holiday times, even when these occur between Mon-Fri, counts as outside of normal operating hours.

If there is any reason to question whether a person can be scanned, they may NOT be scanned until the operator has written permission from the Director or Safety Officer (signature on Pre-Screen Form 1).

Scanning sessions last approximately 0.5-2 hours. Prior to arriving at the Centre, each subject should be screened to make sure that there are no

potential contraindications for MRI (see Form 1 for 1.5T or 3T). If there are potential contraindications such as surgical screws, bolts, cardiac stents, orthopedic implants, joint replacements, intrauterine devices, and so on, and the participant is not a healthy young adult (e.g., easily substitutable), the research lead must send a completed MRI safety form to the Centre Director or BUCNI-director-appointed safety-trained evaluator. The participant **MUST NOT BE SCANNED** without written confirmation via a returned safety form that it is safe to do so.

The form is now online and sent directly to BUCNI:

https://uclpsych.eu.qualtrics.com/jfe/form/SV_38kG6VV1Xun9dxY

When the subject arrives at the Centre, the Centre-Certified Operator will go through the checklist on the relevant Form 1 again with the subject. If the subject is not sure about the answer to any of the checklist questions on Form 1, they will not be scanned. Pregnant women will be excluded from studies at the Centre. Although “to date there are no known deleterious effects related to the use of MR procedures during pregnancy” (Sawyer-Glover and Shellock, 2000), FDA guidelines indicate that the safety of MR for imaging the foetus has not been established.

If there are no contraindications for MRI, the subject will lie on the bed outside the magnet and be positioned in the head coil. Foam pads will be placed around the subject's head for stabilization. Alternative head movement constraints may be used as long as the comfort of the subject is maintained. The subject will be given ear-defenders and instructed in their proper use. Usually a button-press response box or a joystick will be positioned where it can be manipulated by the subject. The emergency squeeze-ball will be placed in or near the subject's hand, and the subject will be instructed how to use it. No cables should touch the subject's skin. Looped cables should not be placed near the subject, and the subject's body should not form any arcs, C- or S-shapes as they could induce electrical current. Any unused cables, transmit or receive coils, or any other unused equipment should be removed from the bore and from the RF coil. Any equipment to be brought into the magnet room must be approved in writing for MR compatibility by the Centre. MR compatibility must be documented on the Centre's MR compatibility list (console room wall). The bed is then advanced into the magnet at a rate of ~8 cm/s through a computer-controlled interface. If, at any time, a subject becomes unable to tolerate the procedure, the exam will be immediately terminated.

Subjects will be in constant communication with the operator via an intercom system (for hearing participants) or via a video system (for hearing-impaired participants). *Subjects who cannot communicate reliably with the console operator cannot be studied.* Although there are no known long-term cumulative effects of exposure to the electromagnetic

fields used in MRI, it is prudent to limit the number of studies on a single individual.

Although MR is extremely safe, no technique is risk-free. Consequently, we have implemented the procedures described in this document as well as yearly reviews of our safety record. The result of the reviews informs changes to policies and procedures to further enhance safety. The primary risk with MRI is from metallic objects brought into the scanner room that could become projectiles. To minimize this risk, nonessential personnel are excluded from the scanner room to ensure that no ferromagnetic objects are brought near the magnet. Reviews by Sherlock and colleagues (see www.mrisafety.com) of the few cases where metal objects caused injury during a scan have found confusion about who had the authority and responsibility to prevent metal objects from entering the scanning room. At BUCNI, it is clear that the ultimate responsibility always lies with the console operator.

Subject Policies

Subject Confidentiality

All records will be kept confidential. Following Centre specific format, a participant number will be recorded in the computer database for the scanner, along with a record of each of the pulse sequences used for the study. This record will be archived¹. No identifying information will be stored except the number provided by the PI. In this way the subject's anonymity is preserved while allowing the Centre to maintain records of the procedures used in each study.

Ethics and Consent

All research subjects may be scanned only after obtaining an approved Ethics protocol.

All research subjects must give their informed consent before taking part in an MRI study, and must pass both the Research Subject Pre-Screen (Form 1) and Operator Checklist (Form 2).

Subjects with metal fragments in brain, eye, auditory canal, spinal cord, or internal organs may not enter the magnet room.

¹ in addition to details added on console computer these have to be entered into the scanning log

Neurological anomalies discovered in the course of scanning

If the scanner operator or other researchers note the presence of an anomaly in a scan, they should Fred Dick immediately after they notice the anomaly.

Importantly, the scanner operator and/or researchers themselves should not tell the subject about any suspected anomalies and should carry on as normal during scanning; the Centre Director and Study PI will decide upon the appropriate course of action once alerted. If the atypical feature in the scan is potentially clinically relevant, the Centre Director will consult with a neuroradiologist, who will evaluate the scan and recommend a course of action.

Screening

The Centre does not allow for study of:

- subjects with non-removable transdermal patches,
- pregnant women or women undergoing fertility treatment (note that there is no evidence that MRI can harm the fetus).
- Subjects with whom no reliable communication can be maintained may not be scanned at the Centre.

As noted above, subjects must be screened for the presence of implanted or attached medical devices or other objects. For screening purposes approved forms have to be completed during recruitment into a study, and before a subject enters the magnet room. Subjects **MUST** be re-screened each time they are scanned.

Only a Centre Certified Operator should perform the screening prior to a study.

To permit an individual who screens positive for implanted or attached medical devices to enter the magnet room requires written permission from the Centre Director or the Safety Officer. They will require the name of the device, its manufacturer, and its part number, as well as a statement from the individual's GP. After the device is identified, documentation of its MR compatibility and safety is required. Please make sure to evaluate participants as far as advance as possible in that these decisions cannot be made on the fly.

Devices

Any non-BUCNI device (e.g., keypads, pulse-ox monitor, eye-tracker) must be approved in writing by the Director or the BUCNI MR physicist before it enters the magnet room.

Device approval must be documented on the MR Device Compatibility List (console room wall).

Special care will be given to positioning of any wires attached to the device. Wires should not touch the research subject. Wires should be kept straight and not contain loops.

Emergencies

Including: fire, power failure, oxygen depletion, and accident.

In the event of any emergency remove the subject from the magnet bore.

Important: in the case that emergency personnel are needed, they should not enter the magnet room itself unless it is absolutely necessary. There is a serious risk that metallic objects such as steel implements will be brought in by accident.

Oxygen Depletion

The magnet room is equipped with oxygen monitoring. The control panel indicating the oxygen level within the room is on the wall of the control room. Should the oxygen level alarm sound then the magnet room must be evacuated immediately. Non-essential staff will also be evacuated from the entire suite. The doors to the corridor and the control room should be kept open to allow rapid restoration of oxygen levels. Two staff must remain on hand to maintain security of the area. These staff should reset the alarm when the panel shows that the oxygen level has returned to normal.

Ferromagnetic Objects

If a metal object traps a subject in or against the magnet bore and removal is not possible without quenching the magnet, press the Magnet Rundown System button on the RIGHT hand wall next to the control room window. The magnetic field will immediately drop to a level where metal objects can be removed. THIS IS A MEASURE OF LAST RESORT.

Quench

If possible, the magnet room should be empty of all personnel and participants before a quench takes place.

A quench is accompanied by a loud bang, causes the rapid loss of the magnetic field, and runs the risk of a helium leak

Any helium or nitrogen gas that might leak into the magnet room can displace oxygen. The Centre's magnet rooms are equipped with vents to provide proper disposal of cryogen vapours. However if the vents should

fail, there is a risk of asphyxiation or frostbite. If the vents should fail during a quench, the operator MUST turn on ALL remaining working fans and open the doors to the operator room and to the magnet room to permit the ventilation of helium or nitrogen gas from the magnet room. Next the subject should be removed from the magnet.

Medical Emergencies

In the event of a medical emergency - call the UCL Emergency Number 222 and follow the instructions of the emergency operator.

We do not currently support a crash cart or defibrillator.

All unit operating staff will attend a minimum of a one day first aid course (Emergency Responder or Appointed Person).

Use the First Aid Kit to manage minor injuries. Gloves should be used when managing minor cuts/ contact with body fluids. See UCL policy on blood and body fluid precautions.

Fire

Fire Action information boards are located by the console room exit and by the Centre exit door.

If you discover a fire operate the nearest fire alarm. There is a fire alarm by the Centre entrance. Dial 222 on a UCL internal phone and follow instructions.

If a fire occurs in the magnet room:

1. Press the Emergency Off button. This is the red button on the upper LEFT side of the console keyboard (not the quench button on the right). There are equivalent Emergency Off buttons placed within the magnet room. Pressing the button cuts power to the magnet room and removes electrical power to all components of the system other than the static magnetic field and the Magnet Shutdown Unit.
2. Evacuate the subject and leave the magnet room, exit to the main corridor by the fire extinguishers.
3. Call 222 and push the fire alarm.
4. Having assessed the fire from outside the room, ONLY trained personnel should use the fire extinguishers to contain the fire. The fire extinguishers located at the entrance to the MRI Centre are magnet-compatible.
5. If the fire alarm sounds leave the MRI Centre and exit the building via nearest fire exit. The assembly point is in the rear of the building south of Gordon Square.

When the Fire Brigade arrive, the Centre Safety Officer or Certificated Operator must make themselves known, and initially prevent fire-fighters

from taking ferromagnetic objects into the magnet room. In the unlikely event that fire-fighters must bring ferromagnetic equipment into the magnet room, quench the magnet by pressing the button on the Magnet Rundown Unit. The Magnet Rundown Unit is on the right hand wall next to the control room window.

Emergency Evacuation

Circumstances which would require an emergency evacuation are:

- Fire: see above
- Power Cut: emergency lighting will engage. The Operator will have to unlock the patient table and manually move the participant out of the bore. After the participant is out of the scanner room, the Operator should guide all other people out of the magnet suite.
- Bomb threat: The Operator should immediately remove the participant from the bore of the magnet, lock the door of the scanner room, and await instructions from authorities.

Operator Illness

See 'Lone Working'

Lone Working

During normal working hours (9-6 Monday-Friday), it is possible (although not advisable) for a BUCNI Trained Operator to run participants without being accompanied by a second safety-trained person. However if there is only one operator, that person should contact a responsible person outside by prior agreement every hour. Failure to maintain contact will result in a call and/or visit from the named responsible person who must be aware of safety procedures within the unit and how to contact further assistance if necessary.

Lone working is fine when conducting administrative work and computing but not encouraged during scanning. In general, it is best to have at least two safety-trained users (at least one of whom is a trained operator) present at all times.

For scanning outside of normal working hours (outside Monday-Friday 9-6), one trained operator and one additional safety trained user must be present when scanning healthy adult participants. When scanning special populations, children aged 16 or under, or persons over 65, an experienced

trained operator and an approved safety-trained user should be present (see table p.14).

Researchers should pay particular attention to their personal safety, and that of their subjects. Scanner operators are responsible for assuring that the MRI suite is secure, and that the doors to the magnet room and console room are locked. The telephone numbers of Siemens Uptime and/or the Centre Director are displayed in the magnet control room for any out-of-hours magnet problems (e.g. helium boil-off).

Manuals

This Safety Manual must be in the control room whenever a subject is being scanned.

Signage

All hazards are clearly signed, including magnetic risks, important devices (quench button), and areas of limited access.