1. Purpose

This policy sets out the management of risks associated with Magnetic Resonance Imaging.

The aim of this policy is to ensure a safe Magnetic Resonance Imaging service for patients, participants, students and staff at the Brain Research & Imaging Centre (BRIC).

This document details the requirements and responsibilities with regard to equipment, facilities and procedures with particular reference to MHRA Device Bulletin 'Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use' (2014)

2. Glossary of Terms

MR SAFETY EXPERT: designated professional (Medical Physicist) with adequate training, knowledge and experience of MRI equipment, its uses and associated requirements. Provides scientific advice to the MR responsible person and MR Lab Heads.

MR RESPONSIBLE PERSON: holds delegated responsibility for the day-to-day operational safety of the BRIC MRI Facility. Maintains close contact with the MR Safety Expert, MR Lab Heads and BRIC MRI Management Group. Maintains appropriate links with regional and / or national bodies as required. Ensures adequate written operating procedures are issued in consultation with the MR Safety Expert and representatives from the MR authorised personnel as appropriate (e.g. radiographers, anaesthetics staff when required).

AUTHORISED PERSON (Non-MR environment): may access the MR controlled access area but NOT the MR environment.

Examples: Cleaners, working out of hours. Radiologists reporting from the MRI Office at BRIC; University of Plymouth (UoP) staff or students preparing research projects in the MRI Control Room.

MR AUTHORISED PERSON (MR environment): has free access to the MR environment but may not supervise others.

Examples: Radiographic helpers, radiologists and medical physicists who work regularly in MRI; UoP staff and students who work regularly with MRI; MR engineers.

MR AUTHORISED PERSON (supervisor): has free access to the MR environment and may supervise others. Are required to comply with this policy, procedures and patient group directives as appropriate. Are responsible for ensuring annual competencies are completed and for maintaining awareness of updated policies and procedures.

Examples. BRIC Radiographers; Senior UoP MR Research Staff.

MR CONTROLLED ACCESS AREA: the area comprising: MRI Cannulation Area; MRI Control Room; MRI Equipment Room and the corridor connecting these areas. Access is restricted and controlled by MR authorised personnel

MR ENVIROMENT: this area is limited to the MRI Exam room, which contains the MR magnet, the 0.50 mT field contour (the 'pacemaker line') and the projectile risk area (≥ 3 mT field).

3. PERSONNEL AND SITE DETAILS

3.1. DUTIES

- The Clinical Director and Radiology Service Line Cluster Manager have overall responsibility for safety in the BRIC MR Facility during UHPNT operated periods. The BRIC Director and MRI Lab Heads have overall responsibility for safety at all other times.
- Guidance from the UHPNT MRI Safety Group (including input from the Trust Radiation Protection Committee and to the MRI Service Improvement Group (SIG)), will be reported to the BRIC MRI Management Group quarterly, to ensure compliance with relevant legislation and national guidelines and best practice, through updating of BRIC Safety and Risk Policies.
- Day to day responsibility for MRI safety is delegated to the responsible MRI Radiographer or Research MR Operator.
- During UHPNT operated periods, the tasks to ensure safe systems in the MRI units are delegated to the clinical lead for MRI and the MRI lead radiographer. These tasks reside with the MRI Lab Heads at all other times.
- All staff working within the MRI suites have a duty to comply with all MRI policies and procedures.
- The MRI Physicist will act as the MR Safety Expert (as defined in the MHRA guidelines 2014) and will act in an advisory capacity to cover the engineering and scientific aspects of the safe clinical use of the MR devices and will be a key member of the MRI Safety Group.
- The MRI Clinical Lead (as SIG lead for the area) is responsible for reporting into the Directorate Board (UHPNT) and BRIC MRI Management Group (UoP).
- The MRI Lead Radiographer and MRI Lab Heads are responsible for investigating any untoward incidents in MRI, taking any action necessary and reviewing relevant risk assessments.
- During UHPNT operated periods, the Consultant Radiologist in charge of each session will be responsible for all clinical matters relating to that session.
- All medical and paramedical staff working in the MRI units will be responsible to the Consultant and/or Radiographer in charge of the session.
- The MRI Lead Radiographer (UHPNT) and MRI Lab Heads (UoP) are responsible for ensuring that all MR authorised personnel, from their respective organisations, receive adequate training and that radiographers and operators have documented competencies which are reviewed and updated annually.
- Radiographic staff from UHPNT and UoP are responsible for ensuring they complete their annual competencies and safety training when requested.
- Radiographic staff are responsible for ensuring that there are two MR Authorised persons (MR environment), within the BRIC MRI Facility whenever the scanner is in use. Both persons must hold up-to-date training, as evidenced by competency and safety documents.

3.2. SCANNER LOCATION

- The scanner (3-Tesla Siemens Prisma) is located within the BRIC MRI Facility, on the ground-floor at the North end of the BRIC building. BRIC is a 2-storey unit located at the West end of the DDRC Healthcare Facility on Plymouth Science Park.

3.3. RISK ASSESSMENTS

- It is the responsibility of the MRI Lead radiographer and MRI Lab Heads, to ensure all hazards and risks are identified and assessed by a suitably experienced and qualified person. These

should be escalated to the Radiology Services Manager and BRIC Director if not able to be controlled locally or eliminated, and entered on the risk register with an action plan.
- Risk assessment and advice on exposure to magnetic fields and radiofrequency radiation should be sought from the MRI Physicist (MR Safety Expert) as appropriate.
- The outcomes of all risk assessments shall be communicated to the MRI team and will inform operating procedures, local rules etc. to ensure safe working practices.

3.3. QUALITY ASSURANCE.

- Physics Quality Control checks are carried out at the commissioning stage of a new scanner.
- Weekly breast coil QA and monthly physics head coil QA will be carried out, Physics will review these data and communicate the findings to the MRI Lead Radiographer as follows:
    - 'Green' i.e. image quality acceptable.
    - 'Amber' i.e. findings to be discussed with scanner engineers at next service
    - 'Red' i.e. significant image quality issues identified, engineer call out required (may / may not need to cease scanning).
- Routine Quality assurance tests are carried out by radiographers in accordance with the manufacturers' recommendations i.e. weekly. The scanner software designates these tests as 'pass / fail'. The results of the tests are documented in the QA folder by the radiographer. In the event of a fail, the test is repeated and then logged with the scanner manufacturer if still failing.
- Scanners are serviced according to the manufacturers' recommendations / service schedule.
- Any image quality problems are investigated via the MRI Image Issues mailbox action is then taken depending on whether it is an operator or equipment issue.
- Quality concerns for research scans should be investigated with the MR Physics and MR Lab Heads.
- Ongoing image quality problems are highlighted to the MRI SIG group.
- There is ongoing audit of image quality, discrepancies and recalls.

4. REFERRAL AND DOCUMENTATION

4.1. Clinical (UHPNT) Process

- Requests are made electronically. Other forms of written / paper referral may be accepted by local agreement.
- Electronic requests are uploaded / transferred onto CRIS. Paper requests are booked onto CRIS upon receipt in the department.
- The requests will be protocolled (vetted) by Consultant Radiologists (or by radiographers in accordance with locally agreed Departmental Operating Procedures) with clear instructions regarding sequences and contrast and accorded priority based on clinical need.
- The MRI booking clerks will allocate outpatient appointments into the appropriate sessions, and inform the patients by letter or by phone if the appointment is being arranged at short notice.
- MRI radiographers will manage in-patient requests based on clinical urgency as indicated by the protocolling radiologist, and available capacity.
- Out-patients are asked to telephone the department if they answer 'yes' to any of the questions on the appointment letter, the questions are designed to provide early notice of any implants that might require investigation. If they fail to do so they may have to be reappointed.
- All scan details should be entered onto the CRIS system; patient ID check, safety and contrast agent questionnaire should also all be scanned onto CRIS. (See linked document – MRI CRIS post examination checklist)

4.1.1. IMAGE PROTOCOLS

- These are authorised by the 'Protocol Lead' radiographer and Clinical Lead or radiologist with responsibility for the appropriate speciality within MRI.
- Controlled documents are held on Q Pulse, and a hard copy (back-up in case of failure of Q Pulse) is kept available in the department (Mansfield Office).

4.1.2. CHECKING PRIOR IMAGING

Radiographers will check the UHPNT CRIS / PACS system only for recent (as indicated below) previous and currently pending requests for patients using the clinical identifiers provided by the referring clinician.

- If duplicate historical requests (see below) for the same clinical indication are found, and the previous reports do not request follow up MRI, or if the request isn't part of a planned series (e.g. surveillance, brachytherapy treatment), the Duty or on call radiologist will be contacted and asked to review the current request.
- If duplicate pending requests (see below) for the same clinical information are found, the Duty or on call radiologist will be alerted (for urgent IP requests), or a note will be placed under the event that has yet to be performed to alert the vetting radiologist or bookings team.

If a radiologist is unavailable to check and the patient is in the department, the default is to perform the scan, unless for a contrast scan for a patient with an out of range eGFR.

Routine out-patient / GP referrals:

- Check for duplicate, previously performed, MRI requests (typically within previous 3 months)
- Check for duplicate, previously performed, other modality requests of the same body part (typically within previous 3 months)
- Check for pending MRI requests of the same body part.

Urgent out-patient / GP referrals:

- Check for duplicate, previously performed, MRI requests (typically within previous 2 weeks).
- Check for duplicate, previously performed, other modality requests of the same body part (typically within previous 2 weeks)
- Check for pending MRI requests of the same body part.

In-patient requests, including on-call and ED:

- Check for duplicate, previously performed MRI request (typically within previous 48 hours).
- Check for similar, previously performed, other modality examinations (typically within previous 48 hours).
- Check for pending MRI requests of the same body part.
- Check for pending similar other modality examinations.

4.1.3. PATIENT IDENTIFICATION

- All MR staff - Radiographers and Helpers greeting patients, should check the patient's details in accordance *with DOP I1.0 Procedure* to ensure correct identification of the patient.

The use of patient labels can facilitate work flow, and assist with labelling forms (e.g. contrast forms, safety forms, documenting the ID check etc). Where labels are used in this way, it is the radiographer's responsibility to ensure the labels are correct in relation to both the patient ID information and examination information held on CRIS. The indications for the examination and the examination requested MUST still be checked against the electronic record.

- Before taking the patient into the exam room the Radiographer should ask the patients Name, Date of Birth, and Address. The address label should then be ticked and signed by the Radiographer, this is scanned onto the CRIS system.
- For in-patients, the radiographer may check the patient wrist band, the three point ID check would then be name, date of birth and hospital number.
- Photographic ID (e.g. driver's license) may also be used if a patient is unable to communicate.
- The radiographer undertaking the safety check MUST sign the form at the time of making that check i.e. when with the patient.
- The Radiographer scanning the patient should ideally be the individual who undertakes the safety screening and identity check, and positions the patient in the scanner.
- A 'pause check' will be undertaken by the MRI radiographer before taking the patient into the scan room confirming all safety and ID requirements have been met.
- If a radiographer who has not undertaken the safety check takes the patient into the room, they must 'pause check' that the safety form has been completed and signed by both the patient and the checking radiographer. They must then also sign to say they have taken the patient into the room – this provides an acknowledgement that they have read the safety information but are also taking responsibility for ensuring the patient is suitably prepared (i.e. 'de-metalled').
- Before commencing the scan, the radiographer must undertake a second 'pause check' and ensure all patient details are correct on the scanner.
- When administering a contrast medium the Radiographer/Radiologist should check the patients name on the form and with the patient. He/she should then obtain permission from the patient to administer the contrast.
- **It is the responsibility of every member of staff to ensure that they have correctly identified the patient in their care.**
- The radiographer will also verify that the examination requested matches the patient's clinical history. In the case of extremities, the radiographer will double-check with the patient which laterality is to be scanned. The radiographer will indicate that they have checked that the requested examination (and laterality when applicable) is correct by ticking the examination indicated on the label (or request card).
- The radiographer will also check the previous imaging history to ensure that the MRI scan is indicated, appropriate and timely.

4.1.4. VOLUNTEERS

- Any person who volunteers to have an MRI scan e.g. member of staff / member of public as part of a test for new techniques or scanners, must have the risks explained to them.
- They must sign a volunteer form (see linked forms – MRI 'cardiac applications volunteers', 'general applications volunteers', 'patient applications consent form upgrade', 'patient applications consent form', 'patient new protocol consent form', 'research applications volunteers')) and undergo safety screening as per *DOP MRI:2 Safety Screening Procedure* before being permitted entry into the scan room.
- They must provide their GP details and give consent for any incidental finding to be relayed to their GP.
- If a volunteer is being scanned as part of a research trial or research study, this must have gained approval from the local Research Ethics Committee. If volunteers are being scanned for service development, the project must be discussed with the research department to ensure it is service development and not research, and that ethical approval is not required. This must be confirmed in writing and a copy of this discussion submitted to the MRI SIG.

- Volunteers should not be scanned if they have a prior known abnormality in the region of investigation.
- All volunteer MRI scans are to be reviewed by a radiologist and entered onto CRIS. Any incidental findings that need further investigation or treatment will be reported back to their G.P.
- Non research volunteer scans should only be arranged when there is a clear service need e.g. during applications training. Service development projects are described above. Volunteers must NOT be scanned to trouble-shoot artefacts / errors. In this cases, the manufacturers and / or physics must be contacted and may elect to use phantom studies.
- Contrast is NOT given to volunteers.
- Orbit radiographs are NOT performed on volunteers.
- Patients may be asked to have their scan with the applications specialist in attendance e.g. whilst introducing new techniques / gaining familiarity with a new scanner. In these cases, the patients will be made aware of this by means of an Information sheet (see linked forms – MRI 'cardiac applications volunteers', 'general applications volunteers', 'patient applications consent form upgrade', 'patient applications consent form', 'patient new protocol consent form', 'research applications volunteers')) included with their appointment letter. They are given the opportunity to state a preference for a non-applications' appointment with the reassurance that this will not influence their care in any way.
- How to book a volunteer onto CRIS for a study is described in Q Pulse MRI Misc 7 – Booking in Test patients, and this protocol MUST be adhered to.

4.2. Research (UoP) Process

- Research participants, taking part in any MRI exam must have the risks explained to them.
- Participants must complete a full consent and screening form before attending the MRI Facility. This process will provide a unique participant identifier that they must use to complete all subsequent forms.
- When arriving at the MRI Facility, participants must re-complete a screening form with an MR Approved person asking each question and explaining if necessary.
- Participants must provide their GP details and give consent for any incidental finding to be relayed to their GP.
- All research trials or studies must have gained approval from the UoP Research Ethics Committee, and the ethics approval number should be included on all documentation.
- A study specific brief must be provided to, and read by, the participant. Questions must be addressed by a member of the study team and a study specific consent must be completed prior to any scanning.
- Participants in research scans will be logged on the system using their unique participant identifier rather that their name, for data protection purposes.
- Participants must be provided with a debrief form following their scan(s) and provided with an opportunity to ask any questions.
- Participant DICOM data will be transferred to the BRIC Orthanc server at the end of the session.

5. SAFETY

5.1. ACCESS TO THE MR CONTROLLED ACCESS AREA

- Access to the MRI units is controlled (restricted) by combination locks / authorised swipe card entry.

- The MRI Lead radiographer and MRI Lab Heads may grant the status of authorised personnel to persons working in the MRI units.
- Authorised personnel (MR environment and supervisors) are those deemed to have sufficient knowledge of MRI safety and working practices, and are required to have frequent access to the MRI Exam Room and Controlled Area.
- All authorised personnel (MR environment and supervisors) will hold the relevant up-to-date safety training and approval documents.
- While a range of staff, including regular engineers, and radiologists, MRI helpers, students etc may be designated an 'authorised' persons (MR environment), only MRI trained radiographers (supervisors) and Senior MR Operators can undertake MR safety screening.
- All individuals granted permission to enter the inner controlled area will be supervised by the MRI radiographer (UHPNT) or Senior MR Operator (UoP) and their well-being remains the responsibility of the MRI radiographer at all times.
- Authorised personnel (MR environment and supervisors) must read, sign and comply with this policy. A list of signatories is kept on file (Mansfield office for UHPNT and BRIC Director Office for UoP). Authorised personnel (Non-MR Environment) are required to read and sign the 'Authorised personnel (Non-MR Environment) statement and signature sheet' before being granted access, which will be supervised by an Authorised (MR Environment) person.
- Cleaning will be scheduled during operational hours, so safe access to controlled areas can be managed by authorised staff.

5.2. SAFETY SCREENING / ACCESS TO THE MR ENVIROMENT

- Access to the MRI Exam Room is only permitted for Authorised Personnel with up-to-date training and approval documentation.
- Access to the MRI Exam Room requires the removal of all ferrous, non MR-safe or MR-conditional items, and any other items likely to affect or be affected by the MRI scanner prior to entry.
- The MRI radiographer or Senior MR Operator has the right to REFUSE entry to the MRI Exam room, if they have any concerns about safety.
- BRIC does not routinely permit access to the MRI Facility for assistance / service dogs. However, the particular needs of a patient will be considered on an individual basis by the MR Lead. Ability for such access will also be contingent on ability to comply with all relevant health and safety requirements.
- In the even that an animal accompanies a patient/participant, all equipment in contact with the animal must be cleaned thoroughly afterwards.
- **It is the responsibility of the radiographer or senior MR operator taking a patient, participant or other individual into the MRI Exam Room to make sure that person is safe to be in that environment.**
- **Records of training and approval will be held by the MR Responsible person (UHP) and MR Lab Heads (UoP).**

5.3. FINAL CHECK BEFORE TAKING A PATIENT/PARTICIPANT INTO THE SCAN ROOM

- A final check for ferrous objects, watches etc. should be made before going into the scan room.
- Ferrous metal detectors are available to help with this process.

5.4. PAUSE CHECK

- Before commencing the scan, the scanning radiographer will perform a pause check i.e. to ensure that:
  - All safety screening requirements (including for contrast) have been met.
  - The patient/participant in the scanner has been correctly identified, and is the referred patient or expected research participant.
  - For patients, the details for the patient selected from the worklist match the referral details.
  - For patients, that the clinical history and prior imaging has been considered, including whether this is a duplicate request, and the MRI scan is indicated, appropriate and timely.
  - For patients, that the patient has been positioned for the correct examination, and where that examination is an extremity, that the correct laterality has been selected,
  - That appropriate coils have been selected and that the patient/participant is positioned correctly (no looping of cables, linking of hands / crossing of legs etc
  - That the orientation selected on the scanner is correct so that all applied anatomical labels will be correct.
- The radiographer will initial the relevant documentation to indicate they have complied with the pause check requirements.

5.5. CHAPERONES

5.5.1. UHPNT Clinical Operation

- In accordance with Trust Policy any patient may request a staff member to act as chaperone for an examination. In MRI this is taken to mean the 'set up for' the scan and the 'removal from' the scanner (this is distinct from an anxious patient requesting company during the scan itself). The name of any staff member acting as chaperone must be recorded on the safety questionnaire.

- All patients MUST be provided with a chaperone (to be a staff member) if undergoing an *intimate* examination e.g. of the breasts, genitalia or rectum although a friend or relative may also be present for reassurance. The name of the staff member acting as chaperone must be documented on the safety questionnaire.

- In accordance with Trust Policy, it is mandatory for all children under the age of 16 to be seen in the presence of another adult. In MRI the requirement for a chaperone is taken to be during the 'set up for' the scan and 'removal from' the scanner. This may be a parent acting as an informal chaperone for general (non-intimate) scans. If the parent / carer does not wish to chaperone their child, a staff chaperone must be provided. The name of the individual acting as chaperone must be documented on the safety questionnaire.

- For children under the age of 16 undergoing an intimate examination, a formal chaperone (i.e. staff member) must be present but a parent or carer may also be present for reassurance.

- In all cases, it is not mandatory for a formal or informal chaperone to remain in the scan room during the scan if the individual does not require it – this would be a decision for the adult patient, or child and their parent / carer.

- If a patient undergoing an intimate examination specifically requests NOT to be chaperoned, this must be clearly documented.

- Please see the Trust Policy for full guidance, (including guidance around mental capacity and consent for young adults and children over 14).

5.5.2. UoP Research Operation

- All children under the age of 16, or adults with learning difficulties or other identified vulnerability must be accompanied by a parent, guardian or carer to the BRIC MRI Facility.

- The option for the parent, guardian or carer to accompany the child or supervised adult into the MRI Exam Room must be provided, based upon the ability to comply with the safety requirements (e.g. no pacemaker or MR Unsafe implants etc)

- If safety prohibits the parent, guardian or carer from accompanying the child into the Exam Room or Control Room, a chaperone must be made available if requested or deemed necessary.

5.6. VISITING STAFF

- Visiting staff e.g. anaesthetics team, nurses, porters, and researchers, will be screened in accordance with the relevant safety processes and required to read the relevant documents on advice for safe practice in the MRI environment. Records of training, competencies and approval will be held by the MR Responsible Person (UHP) and MR Lab Heads (UOP).

5.7. VALUABLES

- As loose electronic / ferrous items cannot be taken into the scan rooms, personal belongings of patients, participants, students and other visitors to the BRIC MRI Facility will be handled as follows:
  - Patient/participant will be provided with an MR conditional locker key to a locker outside the MR Controlled area. Valuables are placed in the locker by the patient/participant. The key is placed in a receptacle in the MRI Control Room for the duration of the scan. Lockers are monitored using the local CCTV in the MRI Control Room.
  - A small plastic container is provided in each locker to place small items such as rings and ear-rings to avoid loss into small locker gaps.
  - The key is returned to the patient/participant following the scan.

5.8. SIGNIFICANT PATHOLOGY PROCEDURE

- UHPNT Clinical scans: In the event that an unexpected and / or significant pathology is suspected during the scan, the radiographer is required to seek timely advice from a radiologist to ensure appropriate and timely management of the patient.
- UoP Research Scans: In the event that an unexpected pathology is suspected, a sequence of informative scans will be acquired and the participant's GP informed to facilitate follow up.

5.9. CONTRAINDICATIONS

a. Intraocular Foreign Bodies

- Patients or participants, will be unable to proceed with MRI scan unless they first have an IOFB x-ray to confirm the absence of potential risk.
- For patient scans, the request card for the IOFB may be completed by a radiologist or MRI radiographer according to *DOP I 3.0 Procedure concerning Referrers*. The image must be checked by a radiologist or designated radiographer in accordance with *DOP MRI: 9 Procedure for IOFB image comments by radiographers*. The result is documented on CRIS.
- Participants, staff, students, visitors and volunteers are not allowed into the scan room if they have reports of accidents involving metal penetrating the eye.

b. Implants

UHPNT Clinical Scans

- The *DOP MRI:3 Safety Procedure (Implants) ≤ 1.5T scanners* outlines the process for identifying and checking implants.
- Implants can be regarded as MR SAFE, MR CONDITONAL and MR UNSAFE. For implants found to be MR Conditional or MR Unsafe, an alert must be added to CRIS, and the relevant information scanned into the patient's CRIS record.
- There are specific DOPS for the management of patients with specific categories of implants as outlined below. These must be followed but must be used in conjunction with the most recent manufacturer information. If additional procedures are implemented after the issuing of this policy for other categories of implant, they also must be followed.
    - DOP MRI_4 Procedure for performing MRI scans in patients with intracranial aneurysm clips
    - DOP MRI_5 Procedure for performing MRI scans in patients with programable shunts
    - DOP MRI_13 Management of patients with active cardiac implants
    - DOP MRI_17.Hearing Implants
    - DOP MRI_21 MRI Intracranial microsensors
- If there is any uncertainty as the safety of an implant, the patient must NOT be scanned.
- The scanning radiographer is responsible for ensuring that an implant is safe or conditionally safe to scan, and if conditional, that the scan parameters are modified appropriately.
- Any adverse incidents involving implants and MRI MUST be reported externally to the MHRA as well as internally on DATIX.
- If the patient has an implant that can be safely scanned on the 0.31T low field strength (extremity) scanner, but not on the 1.5T field scanner, this must clearly be indicated via an ALERT on CRIS.

UoP Research Scans

- A report of an implant is an exclusion criteria for participation in mainstream (healthy control) research studies.
- In the event that an implant is reported, a research participant may be scanned only when full details of the implant have been provided by the clinicians (e.g. surgeon or GP) involved in the participant's care and the MR Safety Expert has confirmed suitability to continue safely with the scan. Any recommendations provided by the MR Safety expert must be adhered to during the scan process.

c. Pregnancy

- The *DOP MRI:7 Procedure for undertaking MRI in pregnancy* outlines the process for informing and scanning pregnant patients.

- Pregnant staff should be given the option not to enter the inner controlled area during the first trimester.
- Pregnant staff should not remain in the scan room during scanning.
- Pregnant staff who are not MRI authorised personnel (supervisor or MR environment) should be excluded from the MR environment (inner controlled area).
- Patients will be asked whether there is any possibility of their being pregnant. The LMP is also recorded, this is not used to determine pregnancy but should be used to trigger a second check if the LMP is out of date i.e. if the period is overdue, then further questioning should take place. In this scenario, the patient should be asked if they are sure there is no possibility of pregnancy. If they are confident that they are not pregnant the scan can proceed.
- Research MRI scans involving pregnant women will only be permitted following full ethical approval from the relevant authority and consistent with all recommended safety guidance for exposure during scans/visits.

6. INTRAVENOUS CONTRAST AGENTS

6.1. UHPNT Clinical Scans

- Gadolinium-based contrast and Buscopan are given intravenously by radiographers when protocolled by the radiologist. Buscopan can also be given intramuscularly.
- This may be given by a suitably qualified radiographer following an authorised Patient Group Directive – these are held on the Intranet.
- Where the administration of contrast is planned, the patient will be cannulated in the clinical area (not in the scan room). The cannula will, wherever practicable, be left in situ for the duration of the observation time.
- Where the administration of contrast is deemed to be necessary during the scan, the patient will be cannulated in the scan room. The cannula will, wherever practicable, be left in situ for the duration of the observation time.
- Butterflies are not routinely used as they do not provide continued access during the observation period in case of an adverse reaction.
- Please refer to the PGD and safety sheets for exclusion criteria.
- Safety considerations (contra-indications, renal function screening etc) for the use of contrast agents and Buscopan follow the guidance contained within the Patient Group Directives and the Medical Imaging Department Policy D4 Policy for the use of drugs and intravascular contrast media within the Imaging Directorate - Gadolonium based contrast media

6.2. UoP Research Scans

- GAD contrast scans are not routinely approved for research scans in the BRIC MRI facility. Use of contrast will be permitted following full ethics, risk and protocol assessment by the MRI Management Group in consultation with relevant clinical and safety experts.

7. MRI SAFETY GROUP

7.1. UHPNT

- The MRI Safety group comprises the Medical Physicist acting as MR Safety Expert, MRI safety lead radiographer and additional MRI radiographers on a rotational basis. The MR Responsible person may attend when required, but generally delegates responsibility for the organisation of this committee to the MRI safety lead radiographer.
- The group meets quarterly (or more often if required) and reviews policies, procedures, risks, incidents and other safety related issues with a view to improving patient and staff safety within MRI.
- The group reviews and comments upon departmental operating procedures.

- The group is responsible for disseminating MRI safety information, ensuring the department's knowledge base remains current.
- The group is responsible for organising annual safety training for MR authorised personnel (MR environment and supervisors).

7.2. UoP and BRIC Research

- MR safety is the responsibility of the BRIC MRI Management Group, which will meet quarterly, unless a time-critical request for a decision is made. Recommendations for policy and process update will be communicated from the UHPNT Safety Group to these meeting by the MRI Responsible Person or MR Safety Expert.

8. MR CONDITIONAL & MR SAFE EQUIPMENT

- A list of all equipment/items that are MR SAFE (items that pose no known hazards in an MR environment) and MR CONDITIONAL (items that pose no known hazards in a specified MR environment with specified conditions of use) is listed on the BRIC MRI Noticeboard in the MRI Control Room.
- Only equipment that is labelled as MR safe or MR Conditional and/or explicitly listed on the MRI Safe Research List (MRI Control Room Noticeboard) may be taken and used in the MRI Exam Room
- Any non-active equipment/items not on the inventory (e.g. drip stands) must be tested with a suitable test magnet (available in the MRI units) or checked by referring to information from the supplier before being taken into the scan room.
- Any active equipment/items not on the inventory (e.g. drug infusion pumps) must be checked by referring to the manufacturer's information before being taken into the scan room. Such equipment must subsequently be labelled in accordance with the department's labelling system.
- Electronic / monitoring equipment must only be used if it is known to be MR SAFE or MR CONDITIONAL.

9. HAZARDS IN MRI

Due to the hazards associated with the magnets, there must always be two MR Approved memners of staff present during operation of the scanner.

There are three main sources of hazard in the MRI units

a) Magnetic fields – Static field and switching fields

b) Radio frequency electromagnetic pulses

c) Cryogen gas

NB: THE MAGNETIC FIELD IS <u>ALWAYS ON</u> !

9.1. MAGNETIC FIELDS – Static and switching fields

- The static magnetic field may cause adverse health effects such as dizziness, nausea and vertigo and in pregnant females there is potentially a risk of possible effects on the developing foetus. As a precaution staff should minimise their movement and time spent at the ends of the bore and pregnant staff should be given the option of not entering the scan room during the declared term of pregnancy.

- Switching fields (gradients) may cause nerve/muscle stimulation both in patients and in staff or carers who may be in close proximity to the patient during scanning. If staff are required to remain in the scan room during scanning (not a common procedure) then they are required to keep away from the bore and at least at a distance of 'arms length' (estimated to be below guideline exposure limits) to minimise the risk of these unpleasant effects.
- Switching fields may cause current loops in the patient and careful positioning of their limbs and coil leads must be observed in line with safety information provided by the manufacturer.
- The spatial variation of the main magnetic field within the bore (in particular close to the surface of the bore) may be an issue with certain MR Conditional devices causing device malfunction and / or hazardous twisting forces on the device / implant.
- At close proximity to the scanner the attractive forces from the magnet field (approximately at field strength 3 mT / 30 Gauss or greater) may cause loose ferromagnetic objects / items to become projectiles which may lead to injury and / or damage to the scanner.
- Anyone entering the unit must be made aware of the dangers of projectiles before entering the exam room, and all ferrous objects removed and stored in the lockers provided.
- Patients, staff and visitors MUST be checked for ferrous items BEFORE entering the scan room.
- MRI Radiographers and other personnel working in MRI must, in addition to Trust and departmental uniform policy, be mindful of the need to ensure that they are not wearing, or carrying in their pockets, any ferrous or electronic items i.e. ferrous jewellery, hairgrips / accessories, pens / pencils with ferrous components, mobile phones as this can become projectile, cause damage and / or become damaged. Care must be taken by staff who wear spectacles as some springs can be ferrous. Whilst everyone entering the room should check themselves for such items, the risk is that in an emergency, such checks may be overlooked. Hence such items should not be worn / carried when on duty in MRI. Lockers are available for staff.

- Each person going into the exam room must have filled out a safety questionnaire before doing so.

- A torque (twisting force) will be exerted on metal objects such as implants and arterial clips which may lead to injury.

- The magnetic field will interfere with the mechanism of the vast majority of cardiac pacemakers and other electro inductive devices. Patients with such devices MUST NOT be allowed into the scan room, and cannot have a scan.

- There are now MR Conditional pacemakers and electronic devices available. If such an implant is conditionally safe, it may be possible for the patient to be scanned, but the manufacturers guidelines must be strictly adhered to and prior approval sought and given by the MR Safety Expert.

- If a ferromagnetic object is taken into the Inner controlled area, please refer to Appendix A

- Any incidents involving magnetic fields such as projectiles must be reported internally via DATIX (UHPNT) and to the MRI Lab Heads and BRIC Director (UoP). If the incident causes damage to an individual or equipment agencies such as the MHRA, CQC and HSE may also need to be informed.

9.2. RADIOFREQUENCY

- The radio frequency electromagnetic pulses used in MRI may cause adverse health effects such as tissue heating and burns. The RF power is mainly absorbed by the patient and the levels that staff would be exposed to (if they remain in the scan room during scanning) are negligible and estimated to be below guideline limits.
- The patient's or participant's measured (by MR Authorised Person) weight must be entered into the scan details in order for the scanner to accurately calculate the SAR (specific absorption rate) - care must be taken that this is kept to an acceptable level. The patient's height must also be entered where this is an option.
- Wherever possible, patients should be scanned using the lowest possible SAR, and wherever possible, patients should be scanned using 'normal operating mode'.
- On no account should coils other than those supplied or approved by the manufacturer be used with the MRI scanner. To avoid RF burns make sure the patients are adequately protected from cables / wires / leads.
- Damaged coils must be taken out of use and reported to the manufacturer immediately and a repaired or replacement coil used.
- Keep all wires and leads attached to the patient and surface coils as straight as possible, as this minimises the build-up of eddy currents.
- Cables must not be looped, and must not be in direct contact with the patient's skin surface
- If a radiofrequency burn is suspected/sustained refer to Appendix B.
- Any incidents involving suspected radiofrequency burns must be reported internally via DATIX (UHPNT) and to MRI Lab Heads (UoP) and agencies such as the MHRA, CQC and HSE may also need to be informed.

9.3. NOISE

- The scanner-generated noise may cause adverse health effects to hearing and risk of headaches particularly with certain scan protocols.
- For UHPNT Clinical Scans: Personal protective equipment (PPE) is available for the patient and any other persons who remain in the scan room during scanning (earplugs / ear defenders / headset), and MUST be utilised.
- For UoP Research Scans: where scanner noise is such that it poses risk, appropriate PPE must be used to ensure suitable protection is provided. Where 'quiet' scans are used, protection should be consistent with the requirement to mitigate potential harm.
- For individuals for whom the ear defenders are too large (e.g. infants, small children), ear plugs must be used as the neonatal 'MiniMuffs' do not provide adequate ear protection on their own. The MiniMuffs can be useful as a means of ensuring the ear plugs stay in situ, but are not to be used on their own.
- Radiographers must follow manufacturer instructions for the fitting of ear plugs and training is provided, as incorrectly fitted earplugs have been shown to offer significantly reduced protection.

9.4. CRYOGENS

- If cryogen helium (liquid/gas) escapes it will displace atmospheric oxygen. This may occur during handling, storage, or a destabilisation of the magnet.
- This destabilisation (accidental or designed) is known as a QUENCH
- In normal operation, during a quench gases will be vented to the outside of the building.
- However, large volumes of gas will rapidly accumulate, and the venting system may be overwhelmed, causing displacement of oxygen in the exam room. Any persons in the room may be at risk of asphyxiation.
- No member of the MR staff may touch the cryogen filling valves.

- Staff must not enter the exam room during cryogen fills, in accordance with the manufacturer's safety policy.
- No open flames or lighted cigarettes are allowed in the MRI Facility
- The battery operated oxygen monitor in the mobile unit must be checked daily, to ensure it is functioning.
- Due to their very low temperatures cryogens present a risk of causing frost burns. If this occurs, refer to Appendix C.

IN THE EVENT OF AN UNCONTROLLED QUENCH, ALL PERSONS MUST EVACUATE THE MRI UNIT

Please refer to Appendix C

10. FIRE IN THE MRI UNIT

Please refer to DDRC Safety policy and Trust Fire Policy and Imaging Directorate Fire procedure.

- If a fire is suspected, OPERATE THE FIRE ALARM and DIAL 9-999
- STATE LOCATION AND NATURE OF FIRE
- EVACUATE ALL PATIENTS, RELATIVES AND NON ESSENTIAL STAFF FROM THE UNIT
- THE MOST SENIOR RADIOGRAPHER IS RESPONSIBLE FOR ENSURING ALL PERSONS HAVE BEEN EVACUATED
- If a fire is small, and can be tackled without putting any member of staff at risk, then the non ferrous fire extinguisher provided in the unit may be used
- If there is no immediate threat to an individual or individuals, discussion about quenching the magnet must take place. The decision to quench might be taken upon advice from the fire service, fire officer, and supervising MRI radiographer (MRI Lead in-hours, MRI on-call radiographer out of hours)
- The senior LA Fire officer should be briefed as to MRI safety and LA fire crews instructed to only tackle the fire from outside the room
- DO NOT re-enter the unit until authorised to do by a fire officer
- The local fire brigade have been made aware of the existence of the BRIC MR unit and understand the hazards associated.
- Equipped fire officers must not enter the **MRI Exam Room** unless the magnets have been quenched. Fire officers may go in the scan room if they have filled out safety questionnaires and remove all ferrous objects from their persons
- They must NOT take non MR compatible equipment into **the MRI Exam Room**

11. CARDIAC ARREST IN MRI

IN THE EVENT OF CARDIAC ARREST OPERATE THE NURSE CALL BUTTON(LEVEL 3) AND DIAL 999

- Remove the patient from the exam room using the non-ferrous equipment

- Clear the waiting areas of patients and visitors
- Ensure the door is securely shut when patient has been removed
- The resuscitation trolley and AED are located outside the MRI room
- Begin resuscitation until the DDRC team arrives
- **RESUSCITATION EQUIPMENT MUST NOT BE TAKEN INTO THE EXAMINATION ROOMS**
- To ensure patient safety in the event of a Cardiac arrest, or other emergency,
- **THERE MUST BE TWO MEMBERS OF STAFF IN THE BRIC MRI FACILITY AT ALL TIMES**
- Annual practice evacuations are held with radiographer and helper staff to ensure familiarity with the evacuation process.

12. DOMESTIC AND CLEANING PROCEDURE

- Domestic staff entering the unit must fill out a safety questionnaire, *Safety Screening Procedure,* read the information sheet (Appendix C) and have the hazards of MRI clearly explained to them by an MRI trained radiographer.
- All loose items e.g. watches, keys, wallets etc must be removed and placed in the lockers provided.
- It is highly desirable that the same domestic staff should clean the MR units whenever possible.
- Equipment used for cleaning must be checked very carefully by MRI staff to ensure it is safe to go in the scan room.
- Electrical equipment such as vacuum cleaners and floor polishers MUST NOT be taken into the scan room.
- Cleaning within the scan rooms is to be undertaken by MR staff or domestic staff under the supervision of MR staff.
- Training and competency records will be kept by the MR Responsible person.

12.1. PORTERING AND TRANSPORT OF PATIENTS (UHPNT Clinical Scans)

- Ambulatory patients should report to BRIC Main Entrance, where access can be provided to the main waiting area by MR staff in the MRI Control Room.
- In the event that a non-ambulatory patient is brought BRIC for MRI, they must be transferred to an MR Conditional Wheelchair or Trolley at the main wait area, for transfer to the MRI Facility.
- THE NON FERROUS CHAIRS AND TROLLEY MUST NOT BE REMOVED FROM THE MRI FACILITY
- Patient transfer equipment is available in the BRIC MRI Facility to move patients to and/or from the MRI scanner via trolley.
- All staff assisting with moving patients must be checked out for safety in accordance with *the Safety Screening Procedures,* read the information sheet and have the hazards of MRI clearly explained to them by an MRI trained radiographer.

12.2. ESCORTS FOR IN-PATIENTS

- Due to the requirement to have two members of staff in the MRI department at all times, patients requiring scans 'on-call' MUST be escorted by a member of staff from the referring department.
- This member of staff (escort) must be safety screened and it must be established by the MRI radiographer that they are safe to enter the scan room. This must be determined before the

patient is taken into the MR Controlled Area. This is in case the escort is required to enter the scan room in an emergency, to provide assistance to the MRI radiographer.

- If the escort is not safe to enter the MR environment, the patient cannot be scanned until another escort, who can be cleared to enter the MR environment, is able to come to the MRI department to accompany the patient.
- It is the responsibility of the referring ward to determine whether a patient being scanned 'in-hours' requires an escort due to their general level of health. If in the opinion of the referring ward, a patient does require an escort, the ward must provide a suitably qualified escort, depending on their assessment of their patient's condition (e.g. HCA / qualified nurse etc)

12.3. SEDATED PATIENTS (UHPNT Clinical Scans)

- **All** patients who have been given (or taken) sedation prior to their scan **must** be monitored during the scan (e.g. pulse oximetry). In-patients must be accompanied for their scan by an escort provided by the referring ward (as outlined above).
- In addition, if the MRI radiographer has any concerns about the ability of a patient to communicate during a scan, then that patient must be monitored during the scan (e.g. pulse oximetry).
- Infants (neonates) will be sedated and monitored according to the anaesthetics department sedation policy which also stipulates the minimum level and qualification of staff who must accompany the infant.

12.4. OBSERVATION OF THE PATIENT OR PARTICIPANT

- All patients and participants will be provided with the call bell during their scan.
- The radiographer will ensure that the patient or participant can hear them over the intercom before commencing the scan.
- The radiographer will speak to the patient or participant between each sequence, and will seek a response between each sequence.
- If a patient is unable to communicate verbally in this way (e.g. due to general level of health, sedation etc), the patient will be monitored (e.g. using pulse oximetry) as described above (sedated patients).

13. References:

1. MHRA Device Bulletin 'Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use' (2014)
2. Shellock F (2011) *Reference Manual for Magnetic Resonance Safety, Implants, and Devices: 2011 Edition.*
3. www.mrisafety.com
4. American Society for Testing and Materials (ASTM) International, Designation: F2503-05. Standard Practice for Marking Medical Devices and other items for Safety in the Magnetic Resonance Environment. ASTM International, West Conshohocken, PA 2005
5. Proposed Electro Magnetic Fields (EMF) Directive 'Physical Agents (Electromagnetic Fields) Directive 2004/40/EC amended by 2008/46/EC 'available at http://www.hse.gov.uk/radiation/nonionising/electro.htm

6.http://www.mypetsdoctor.com/microchips-are-safe-during-magnetic-resonance-imaging-mri

Appendix A

FERROMAGNETIC OBJECT ACCIDENT

FERROMAGNETIC OBJECT IN OR ON THE MAGNET – NO PERSON INJURED

1. Remove patient and other personnel from the scan room
2. If the object is small easily reachable and you may do so without endangering yourself, attempt to remove the item from the magnet
3. Do not attempt to remove the article if it is large, unstable or you feel that it may be dangerous to do so. If it escapes it will be attracted into the magnet with force and cause even more damage. Contact the manufacturer of the scanner for advice

FERROMAGNETIC OBJECT INSIDE MAGNET WITH UNINJURED PATIENT IN SITU

1. Inform the MRI Superintendent or MRI Lab Heads immediately, or at the first opportunity
2. Assess whether the object is stable. Do not attempt to remove it
3. Reassure patient but do not move table
4. With the assistance of other suitably trained and safety screened staff, evacuate the patient
5. Liaise with manufacturer for advice if possible

FERROMAGNETIC OBJECT TRAPPING PATIENT AGAINST MAGNET

1. Inform the MRI Superintendent or MR Lab Heads immediately, or at the first opportunity.
2. Obtain the assistance of other suitably trained and safety screened staff.
3. Secure / support the object so that upon quenching it will not cause further injury to the patient.
4. Quench the magnet immediately using the ERDU (Emergency Run Down Unit).
5. Remove the patient from the scan room.
6. Evacuate unit because of hazards associated with escaping cryogenic gases.
7. Deal with injuries as appropriate.
8. Contact manufacturer and take advice. Do not re-enter scan room until advised.

For all events, a Datix incident report must be completed, the MHRA may need to be informed (e.g. if incident is involving a patient or personnel) and the incident investigated.

RADIOFREQUENCY BURNS

- These are an unlikely event if care is taken when positioning coils.
- If a burn does occur then the patient should be treated by a member of the nursing staff, and referred to the Emergency Department (E.D.) if necessary. If the burn is reported after the event, the patient should be advised to seek medical assistance.
- A Datix incident form should be completed and the MRI Superintendent or Clinical Lead informed.
- In the event of a burn a record should be kept of all details relating to the incident e.g.
    - Coil used
    - Sequence used
    - ECG leads used?
    - Degree of burn and area involved.
- Manufacturers must be informed and the equipment taken out of use.
- An MHRA report must be completed.

CRYOGEN FROST BURNS

- Do not rub the skin over the affected area.
- Rinse the skin with water and cover with a sterile dressing
- Refer the affected person to the Emergency Department
- A Datix incident form should be completed and the MRI Superintendent or Clinical Lead informed. An MHRA report must also be completed.

Appendix C

ACTION IN THE EVENT OF AN ACCIDENTAL OR UNCONTROLLED QUENCH

- If there is a leak of cryogenic Helium (liquid/gas) an alarm will sound in the scan room once the O_2 level has fallen below 18%
- On hearing the alarm, or initiating a quench, the scan room must be evacuated immediately
- Close the scan room door and DO NOT RE ENTER
- In the event of suffocation due to the leakage of cryogens remove the patient from the scan room and resuscitate immediately, following the procedure for Cardiac/Respiratory arrest (refer to Appendix 4)
- Report the incident to the manufacturer immediately. Follow the advice from the manufacturers and do not re-enter the scan room until it is deemed safe to do so.
- A Datix incident form should be completed and the MRI Superintendent or Clinical Lead informed. An MHRA report must also be completed.

Appendix D

ACTIONS FOR SWITCHBOARD AND DUTY MANAGER WHEN ALARMS ARE ACTIVATED IN MRI SCANNERS

Commented [SDH1]: Section for final discussion with DDRC/UHP/UoP teams

? Duty MRI Radiographer or UoP staff – UHP staff on call from home 2000-0800 M-F, 1700-0800 Sat/Sun – was this involvement agreed originally?

DURING NORMAL WORKING HOURS

- Fire alarm activation
  - Call fire brigade (999)
- Quench alarm activation (Modular B)
  - Contact scanner to confirm that it is not a false alarm.
  - Reassure concerned callers that it is safe.
- Security Alarm/concern
  - Contact scanner to confirm that it is not a false alarm.

OUTSIDE OF NORMAL WORKING HOURS

- Fire alarm activation
  - Call fire brigade.
  - Contact duty MRI Radiographer.
- Quench alarm activation (Modular B)
  - Contact duty MRI Radiographer.
  - Reassure concerned callers that it is safe.
- Security alarm/concern
  - Contact duty MRI Radiographer.
  - Security may check doors and windows but **MUST NOT enter the scan room** until duty radiographer is present.