

## Important Information

- Under no circumstances should this list be given to volunteers.
- This safety information is only applicable to studies using the FMRIB/OHBA Siemens Prisma 3T.
- Without the risk versus benefit analysis that exists for clinical MRI, we must be much more cautious in a research environment.
- Therefore a volunteer that is excluded from having an MRI at FMRIB/OHBA will, in many cases, be able to undergo a clinical MRI examination at a lesser field strength.

## Screening

- It is a requirement that you go through the 3T Volunteer Screening Form at the initial recruitment stage.
- Any 'yes' responses that are not covered by this list must be checked with the radiographers via [MRIsafety@fmrib.ox.ac.uk](mailto:MRIsafety@fmrib.ox.ac.uk)

## Using The List

- Anything NOT on this list must be treated as 'Further Information Required'.

## Using [MRIsafety@fmrib.ox.ac.uk](mailto:MRIsafety@fmrib.ox.ac.uk)

- Any safety queries that are not covered in the list, are classified as 'Further Information Required' or as 'Likely Exclusion', should be sent to [MRIsafety@fmrib.ox.ac.uk](mailto:MRIsafety@fmrib.ox.ac.uk)
- This is a ticketed system and your email will receive a reply with a reference number for the volunteer. Please reply to this acknowledgment email if you wish to add further information.
- Your email should
  - Relate to 1 volunteer only. If you have more than one volunteer with a safety query, each volunteer must have a separate email.
  - The subject line must contain the FMRIB/OHBA study number, field strength, the volunteers DOB and gender, e.g. '2013\_50 (3T) – 01/01/1980 – M'
  - Please include as much information in the body of the email as possible e.g. the procedure/s, reason for surgery, the hospital and country of surgery if not the UK, the manufacturer, model name or number of any implants used.
  - **If you are including supporting documentation eg hospital notes, all identifying information other than DOB must be redacted.**
- The radiographers will then investigate the MRI compatibility of the surgery or implant.
- Please note that manufacturers can take several weeks to provide compatibility information.
- If scanning is approved you must bring a copy of this email to the scanning session.

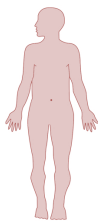
## High Value Volunteers

- In exceptional cases it may still be possible to scan a high value volunteer that has an implant.
- Examples include where manufacturer safety information either doesn't exist or contraindicates scanning, or implant information cannot be obtained.
- Applications to scan such volunteers need to demonstrate that their exclusion will have a significant detrimental effect on the study.
- If an application is accepted, an implant risk assessment will be carried out along with an examination of any ethical and legal considerations.

## X-raying Volunteers

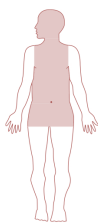
- The use of ionising radiation in a research protocol requires REC approval under the Ionising Radiation (Medical Exposure) Regulations 2002 ("IRMER").
- Therefore you cannot x-ray a potential volunteer to check for clips or foreign bodies without explicit ethical approval.
- If this applies to your study please contact [MRIsafety@fmrib.ox.ac.uk](mailto:MRIsafety@fmrib.ox.ac.uk) for details on how to organise an X-ray.

## Surgery in the last 6 weeks



- As a general rule, a minimum of 6 weeks must have passed between any surgery and scanning
- This also includes diagnostic investigations such as laparoscopy and arthroscopy
- Many implants and surgical clips (that the volunteer may not be aware of) require a period of time for scar tissue to firmly embed them into place
- Other considerations here include whether the volunteer will be able to lie comfortably for the scan and whether they fulfil the study's definition of a "healthy volunteer"

## Endoscopy in the last 6 weeks

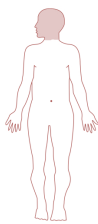


- With very few exceptions, 6 weeks must have passed between endoscopy and scanning
- Some routinely used marking/tagging clips are highly ferrous (the volunteer may not be aware of their use)
- Endoscopy performed via pill camera is becoming more common place
- Both of these could result in serious injury if exposed to a strong magnetic field

## Head and Brain Surgery/Implants

### Safe

- Cysts removed from scalp (as long as no bone was cut), stitches/staples for lacerations (as long as removed and no bone was cut), removal of nasal polyps, septoplasties, tonsillectomies and adenoidectomies



### Further Information Required

- In general any volunteer with a history of brain surgery, including burr holes or biopsies, will be excluded from scanning (the risk comes from clips that may have been used during the surgery and not recorded)
- Other aspects that need to be considered include the presence of any implants including, but not limited to, cranial fixation devices, shunts (fixed or programmable), clips on sensitive structures, stents, coils

### Likely Exclusion

- Volunteers with aneurysm clips, neurostimulators

## Eye Surgery/Implants

### Safe

- Squint correction during childhood, minor cosmetic surgery, laser eye surgery for vision correction, cataract surgery post 2000



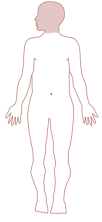
### Further Information Required

- All other eye operations including, but not limited to, squint correction as an adult, surgery for a detached retina, lens implants not associated with cataract surgery, cataract surgery done pre 2000
- All eye implants eg eye prostheses, metal weights in eyelids, eye lid springs

### Likely Exclusion

- Any volunteers with a history of a metallic penetrating eye injury where there is no radiological evidence of it being removed (even if removed medically)

## Ear Surgery/Implants



### Safe

- Grommets (regardless of when they were implanted or whether they are still present), cosmetic ear procedures eg pinoplasmy

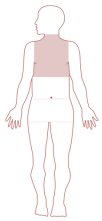
### Further Information Required

- All other ear surgeries eg stapedectomies, stapedotomies, surgery for a ruptured ear drum

### Likely Exclusion

- Volunteers with cochlear implants

## Thoracic Surgery/Implants



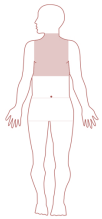
### Safe

- Breast biopsy, lumpectomies, mastectomies (as long as no implants associated with surgery, eg tissue expanders), lobectomies

### Further Information Required

- Breast implants, tissue expanders

## Heart Surgery/Implants



### Safe

- Coronary bypasses (including sternal wiring), diagnostic angiography of coronary vessels

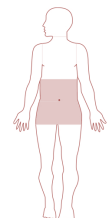
### Further Information Required

- Coronary stents, PFO closure devices, artificial heart valves, if there is any history of a pacemaker or defibrillator that has now been removed (pacing wires aren't always removed)

### Likely Exclusion

- Pacemakers, defibrillators

## Abdominal and Pelvis Surgery/Implants



### Safe

- Appendectomies, hernia repairs involving mesh, cholecystectomies, sterilisations, vasectomies, C-sections, gynaecological procedures using tapes or mesh, endoscopies (after 6 weeks), hysterectomies, prostate surgery

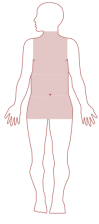
### Further Information Required

- Haemorrhoidectomies, haemorrhoid banding, filters, stents, implanted drug delivery devices, colostomies, cystoscopies, pessaries, insulin or infusion pumps, urinary catheters, penile implants, brachytherapy implants

### Likely Exclusion

- Capsule endoscopy devices eg pill cam (until they have passed)

## Spine Surgery/Implants



### Safe

- Any surgeries that have not introduced any metallic implants eg discectomies, micro-discectomies, decompressions, laminectomies

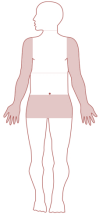
### Further Information Required

- Spinal fusions, Anterior Cervical Discectomies and Fusions (ACDFs)

### Likely Exclusion

- Harrington rods, spinal cord stimulators

## Contraceptive Implants



### Safe

- The Mirena IUS, Jaydess IUS, Nexplanon and Implanon contraceptive implants

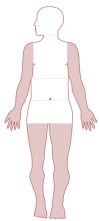
### Further Information Required

- All other IUDs, contraceptive coils and diaphragms

## Orthopaedic Surgery/Implants

### Safe

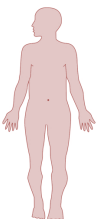
- Arthroscopies, any surgery not involving implanted devices



### Further Information Required

- Volunteers with orthopaedic implants outside the body transmitter coil (the scanner bore) will usually be safe to scan. For head imaging this will generally be from mid thigh down, depending on the volunteer's height. However you must email [MRIsafety@fmrib.ox.ac.uk](mailto:MRIsafety@fmrib.ox.ac.uk) for detailed information.
- Open reduction internal fixations (ORIFs) followed by removal of metallic implants (often removal can be incomplete)
- All joint replacements, ORIFs, bone/joint pins, screws, nails, wires, plates, etc

## Vessel Surgery/Implants



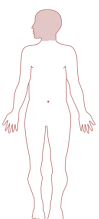
### Safe

- Diagnostic angiography, varicose veins (even if clips are used), vessel grafts

### Further Information Required

- Stents, filters, vascular access ports and/or catheters

## Dental Surgery/Implants



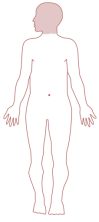
### Safe

- Fillings, crowns, dental posts (entirely within the tooth) associated with root canal treatment, retainers, traditional bridges (non-Maryland type), braces (however there is a potential for artefacts)

### Further Information Required

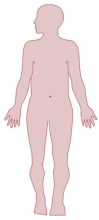
- Maryland bridges, dental implants (are screwed into the jaw) – if we can confirm that they are composed of non-magnetic materials they are safe to scan, otherwise they will be excluded (some older implants are ferromagnetic, some implants contain strong magnets)
- Jaw surgery – need to identify precisely what the volunteer has had done before a decision can be made regarding safety and artefacts

## Metallic Foreign Bodies - Orbits



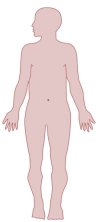
- Any volunteers with a history of an orbital metallic FB should firstly have the risks associated with scanning, including blindness, explained to them
- In cases of penetrative injuries, scanning must not proceed unless there is a written radiological opinion confirming the absence of any metallic fragments
- In cases of non-penetrative intraocular metallic foreign body scanning cannot proceed unless the volunteer can state categorically that all metal fragments have been removed medically
- It is not ethical for a research volunteer to be subjected to x-rays in order to clear them for a research MRI scan. However if a written radiological opinion can be obtained on existing imaging that rules out a metallic foreign body the volunteer can be scanned.

## Metallic Foreign Bodies - Non-Orbits



- Unless the volunteer can state categorically that all of the metal fragments have been removed by a doctor, they will be excluded from scanning.
- It is not appropriate for a research volunteer to be subjected to x-rays in order to clear them for a research MRI scan. However if a written radiological opinion can be obtained on existing imaging that rules out a metallic foreign body the volunteer can be scanned.
- In some cases it may be possible to scan volunteers with metallic foreign bodies in the hands or feet, subject to a risk assessment.

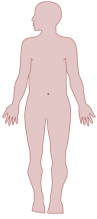
## Miscellaneous



- Artificial limbs, prosthetics eg false eyes, callipers, braces or corsets
  - Must be removed prior to entering the MR CONTROLLED AREA
  - MR SAFE walking sticks or an MR SAFE wheelchair is available at FMRIB if required
- Medicated patches
  - All medicated patches must be removed prior to scanning eg nicotine, contraceptive, pain relief, nitro
  - If the patch is for a prescription medicine the participant must check with their GP that it can be removed safely for the duration of the scan
  - It is recommended that the participant brings a replacement patch as it is not always possible to reapply a patch after it has been removed
- Mascara and Eyeliner
  - Mascara and eyeliner needs to be removed prior to the scan
  - While FMRIB has makeup removing solution it is recommended that participants are warned so they can bring their own remover and makeup to reapply afterwards
- Body piercing jewellery
  - All metallic body piercing jewellery must be removed for scanning
  - Jewellery that is entirely plastic can remain in place
  - It is recommended that participants change metal piercings to plastic piercings prior to attending for their scan (some piercings may have to be swapped by the original piercer)
- Transdermal anchors
  - Participants with transdermal anchors should be excluded from imaging unless there is manufacturer information regarding MR compatibility

- Rings
  - All rings should be removed if possible
  - If not then the radiographer or scanop will check it for ferromagnetic properties
  - If it is not ferrous the participant will be warned regarding heating and to alert the radiographer or scanop if this happens

### **Tattoos, Cosmetic Tattoos and Permanent Makeup**



- Participants with tattoos will be warned of the rare complication of heating and to inform the radiographer or scanop immediately if they feel any heating
- Furthermore participants with new tattoos will not be scanned until 48 hours after to avoid the risk of smearing or blurring