MRI Users Induction Pack (FMRIB)

For those working with the MRI scanner

- FMRIB and Annexe Building Guide
- FMRIB Building Access Request Form
- FMRIB Fire Safety Guidelines
- Magnet Safety Instructions
- FMRIB Accident Reporting Procedures
- WIN Computing Guide
- Data Security
- Responsibility of Researchers with Respect to Ethics
- Authorship Guidelines
- MRI Scanning Guide
- MRI Scanning Service Agreement
- FMRIB MRI Minimum Attendance Policy
- FMRIB MRI Emergency Guidelines
- SOP: Dealing with Neuro Incidental Findings

All these documents are also available on the WIN website at www.win.ox.ac.uk

Prof Heidi Johansen-Berg
Director, Wellcome Centre for Integrative Neuroimaging
FMRIB, Nuffield Department of Clinical Neurosciences
John Radcliffe Hospital, Headington, Oxford OX3 9DU, UK
Tel: +44 (0) 1865 610469   Email: heidi.johansen-berg@ndcn.ox.ac.uk

Welcome to the WIN!

I hope you will have a very stimulating and enjoyable time with us. The staff, students and fellows at WIN strive to make this a pleasant, open and highly interactive work environment.

In this pack we provide information about some of the basic issues related to working at WIN. You will also find extensive guidance and documentation on the WIN website: www.win.ox.ac.uk

You undoubtedly will have questions as you start. Do not hesitate to ask anyone in the lab for help. If you are unsure who to ask about a particular issue, the best first contact point is admin@win.ox.ac.uk. The WIN admin team is happy to help with any queries relating to administrative issues around getting started at WIN, access to our buildings, any issues relating to carrying out research at WIN, etc.

Please also join us at our regular WIN Wednesday meetings. It is a great opportunity to meet people, hear about the research, and hear from some excellent speakers from WIN and beyond. The programme is at www.win.ox.ac.uk/events

I look forward to personally meeting you at some point soon.

With best wishes.

Heidi Johansen-Berg
Director, Wellcome Centre for Integrative Neuroimaging

FMRIB and Annexe Building Guide

How to get access to the FMRIB Building
and Annexe

Working Safely at WIN

It is your responsibility to be familiar with all safety instructions and safe working practices relating to your work in the centre. Key documents will be given to you at your induction, and full documentation is available on the WIN and University Safety Office websites.

1. The MRI magnets are always 'on' and can represent a hazard to those who have not been screened for safe entry. Therefore, no one may enter the 'MR Controlled Area' around the magnet room, or admit another person to that area, unless they have attended the magnet safety-training course.

2. The FMRIB Building and Annexe does not have a 24-hour security patrol, therefore for your own safety you should not work alone in the building after 6 pm.

3. If you admit anyone into the building, it is your responsibility to ensure that they are adequately supervised so as not to represent a hazard to themselves or others. Do not give your university card to anyone else. If you lose or misplace your university card, you must tell one of the IT Team AS SOON AS YOU DISCOVER THE LOSS.

Access

To gain access to the FMRIB Building and Annexe you will need an Oxford University Card. Your Department HR Team should have already arranged this for you. Long-term visitors from outside of the University should be able to apply for a University Card via the HR Team of the Department you are collaborating with.

Before being granted access you will need to create a profile on the WIN registration system, complete a department induction and building induction, and attend a magnet safety training.

1. Register as part of WIN by visiting register.fmrib.ox.ac.uk and creating a profile. Log-in with your single sign-on (SSO) and click on 'update profile' to add any missing details and select your WIN supervisor.

2. Request an induction pack from reception or admin@win.ox.ac.uk, read the information and complete the enclosed building access request form. You can also download this pack from www.win.ox.ac.uk.

3. Attend an NDCN Department Induction, run every Tuesday at 1:30pm online/on Level 6 of the West Wing of the John Radcliffe Hospital. You can book onto it by emailing facilities@ndcn.ox.ac.uk. Make it clear to the person running the induction that you are working at the WIN@FMRIB Building/Annexe and take your access request form with you.

4. Arrange to attend a magnet safety training session with the Centre Radiographers. Upcoming dates are shown on the WIN Intranet, in the weekly Monday Message, and available from admin@win.ox.ac.uk.

5. Return your access request form to reception and arrange a FMRIB building and Annexe tour. Currently building tours are run on Wednesdays at 9.30am but email admin@win.ox.ac.uk to confirm or schedule a different time.

You will then be given card access to the building within a couple of days.

Please note that you will need to attend magnet safety training on a yearly basis in order maintain card access.

There are two levels of access permission granted to staff, students, and collaborators:

Normal access (new students, MSc students, collaborators)

Your card will gain you access to the building between the hours of 6 am – 10:30 pm, weekdays. You may not work in the building unless someone with out-of-hours access is still in the building.

Weekend access (students by request, post-docs, staff)

Your card will give you access to the building between the hours of 6 am – 10:30 pm including weekends. Entering the building using your card will also unset the alarm, but you will need to exit the building before 10:30 pm when the building alarm will automatically set.

In FMRIB, between the hours of 6 pm – 7 am the internal doors leading from the entrance stairwell are locked automatically. Movement around the building during this time requires the use of your University card to enter the area, or through use of the green domed button on exit. In the unlikely event of the domed button not releasing the door, green 'Break Glass' units are provided for overriding the door locks. If you use the 'break-glass' to exit, please inform a senior member of staff so that the seal can be replaced/reset.

Leaving the building

FMRIB

If you are the last to leave the building, ensure that all windows are shut, lights and air-conditioning are turned off.

The security alarm will sound if any fire door is opened or if any door is forced. An alarm will also sound if the main or rear entrance doors are propped open for more than 30 seconds.

If you are in FMRIB and you hear the security alarm after 6pm, for your own safety you should leave immediately by the nearest exit. Call the NDCN facilities out-of-hours number 07521 161 549. If you leave by a 'break-glass' fire exit, please inform a senior member of staff so that the seal can be replaced/reset.

If you have mistakenly set off the alarm, or are otherwise aware of a false alarm, please contact security (call 01865 220 189 from a hospital phone and ask to be put through to security) and wait for them to arrive so that they can reset the alarm with their fob. Please write details in the logbook provided.

Annexe

If you are the last to leave the building, please ensure that the main door closes behind you. Please call the out-of-hours NDCN facilities number 07521 161 549 if it does not close properly. This number is posted in the reception area to the Annexe.

The security alarm will sound if any fire door is opened or if any door is forced.

If you are in the Annexe and you hear the security alarm after 6pm, for your own safety you should leave immediately by the nearest exit. Call the NDCN facilities out-of-hours number 07521 161 549.

If you have mistakenly set off the alarm, or are otherwise aware of a false alarm, please contact security (call 01865 220 189 from a hospital phone and ask to be put through to security) and wait for them to arrive so that they can reset the alarm with their fob.

FMRIB building scanner and computing alarms

There are also a number of alarms associated with scanner instrumentation. If you hear an alarm

going off in the scanner room, then it is usually important that one of the members of the senior staff be notified that the alarm is sounding. If you are uncertain whether someone should be notified, please err on the side of caution and telephone to leave a message anyway.

There are several alarm systems associated with WIN IT equipment located in the network cabinet at the rear of the upstairs open plan office, in the store room at the end of the first floor corridor next to the seminar room and in the server room located at the rear of the IT Office. There is an amber flashing light located in the IT office which illuminates when there is an A/C failure in the main server room.

Any IT related alarm should be classed as urgent and you should attempt to contact one of the Centre IT staff.

A list of contact numbers is posted near the main doors of FMRIB.

FMRIB building workshop

The centre has a workshop principally for the use of the Technical Support staff. This room houses many potentially dangerous items of equipment. You must not use any equipment in this room without the express permission/supervision of Sebastian Rieger (sebastian.rieger@psych.ox.ac.uk).

Other risks in the FMRIB building

A laser warning sign is located outside the magnet rooms. No entry is permitted to the room when the sign is illuminated. If your research involves the use of bottled gases, lasers, TMS or tDCS then you must complete the appropriate training in their safe use. Contact admin@win.ox.ac.uk if you are not sure what training is required.

Manual Handling

Activities that involve the manual lifting or moving of heavy items may only be carried out by individuals that have been on a manual-handling course. Any Manual Handling activity must have been risk assessed prior to taking place; a generic risk assessment is possible where repetitive tasks take place. The main risk activity within the FMRIB Building is the lifting of subjects into the scanner, but also applies to the movement of many pieces of equipment about the buildings. The University runs courses throughout the year which can be booked via the Safety Office website (https://safety.admin.ox.ac.uk). Training in manual handling of subjects for NDCN staff can be arranged via the department Facilities team, (facilities@ndcn.ox.ac.uk).

COSHH/Risk Assessments

Where your experiments require the use of items covered by the Control Of Substances Hazardous to Health (COSHH) regulations or require a Risk Assessment, your supervisor or line manager should complete the necessary documentation on the associated risks. This may already have been carried as part of an ethics approval. If in doubt about any potentially dangerous activity you must consult with your supervisor, line manager, or the Department Safety Officer (facilities@ndcn.ox.ac.uk)

Pregnancy

If you become pregnant you should advise the Department Safety Officer or HR, they will advise on a suitable risk assessment in complete confidence, at the earliest opportunity to discuss changes to your working practices during your pregnancy. Please note that there are no known risks to the unborn child from high magnetic fields, but we recommend that you do not enter the magnet rooms during your pregnancy.

For further information see the pregnant worker risk assessment at www.win.ox.ac.uk.

Kitchen Areas

There is a Common Room on the ground floor of the FMRIB building with tables and a larger seating area for eating lunch and socialising. There are facilities for making coffee, along with a hot water boiler, microwave, refrigerator and chilled water tap. The Annexe also has a small kitchen area on the 2nd floor with a hot/cold water Zip tap and refrigerator.

It is important to try to keep these areas neat and reasonably clean. Please wash your own mugs, or put them in the dishwasher, to reduce the clutter. Also be aware that there are work areas immediately adjacent, so it is important to keep noise down to a tolerable level and consumption of odorous food to a minimum.

The Common Room is primarily a staff area. Unfortunately, we do not have the space for subjects or their relatives to wait before or during scans, other than in the reception area. People who need to wait for more than a few minutes should be encouraged to visit one of the public areas in the main hospital, such as the League of Friends, Pret, or M&S Cafés.

Parking and Bikes

There are no car parking spaces for WIN staff or students immediately outside the buildings. Applications for permits for the staff car park may be made to the OUH Trust, although only people who live a considerable distance from the Hospital are likely to be awarded one. Bikes may be locked to the racks at either the rear courtyard of the FMRIB building, or near the front door. There is a covered bike rack at the entrance to the Annexe.

There are 2 bicycles at FMRIB available for booking and use between WIN sites. These bicycles must be booked via Calpendo (https://calpendo.fmrib.ox.ac.uk) and signed in/out at FMRIB Reception.

Fire Safety Guidelines

General Responsibilities in the Event of a Fire

By signing the enclosed FMRIB building access request form, I accept the responsibility:

1. to understand fully these "**FIRE ORDERS**" and ask for guidance, if in doubt.

2. to prevent possible causes of fire (no smoking, switch off appliances when not in use or last to leave FMRIB Building, especially in the kitchen or workshop).

3. to be familiar with the fire emergency actions (see next page)

4. to raise the alarm immediately upon discovering, suspecting, or hearing report of a fire and to call 4444 from a hospital telephone to confirm a real fire stating: **Fire at WIN Centre, FMRIB Building, adjacent to MRI**. Should you be unable to access a hospital telephone you shall call 999 from a mobile/national network telephone, stating: **Fire at WIN Centre, FMRIB Building, John Radcliffe Hospital, Headley Way, Oxford, OX3 9DU**

5. to know where the Fire Alarm Break Glass Units are located, particularly in your work area.

6. to know where the fire exits are located.

7. to see that these fire exits and all staircases, landing and corridors are kept free from obstructions.

8. to see that all fire exits are immediately and easily available from the inside.

9. to see that fire doors are **KEPT CLOSED** (and **NOT PROPPED OPEN**) at all times and on hearing the alarm to close all doors to prevent the spread of smoke and fire.

10. to know what to do on hearing the fire alarm (see following pages)

11. to report any defects to the Department Safety Officer or senior FMRIB staff.

FIRE ALARM ACTIVATION

1. By breaking the glass on any fire alarm call point (only requires push action).

2. Automatically when heat or smoke from a fire is in contact with the relevant type of automatic detector head, where these are installed.

RAISING THE ALARMS

Any person suspecting/discovering a fire should immediately:

- **CLOSE THE DOOR ON THE FIRE**

- **EVACUATE BUILDING OR**

- **TACKLE THE FIRE**
  (**IF SAFE TO DO SO**)

- **USE NEAREST FIRE ALARM BREAK GLASS UNIT**
  (only requires push action)

- **CALL 4444 FROM A HOSPITAL TELEPHONE TO CONFIRM FIRE WITH NHS TRUST**
  (They will call the fire brigade)

- If you are unable to contact the NHS Trust:
  CALL 999 (9999 from a hospital telephone) TO CONFIRM FIRE WITH THE UK FIRE SERVICE
  State:
  Fire at WIN Centre, FMRIB Building, John Radcliffe Hospital, Headley Way, Oxford, OX3 9DU

There will be **A CONTINUOUS TWO TONE-ALARM** when the alarm is activated.

NOTE: The Fire Brigade will **NOT** automatically attend a fire alarm, so all genuine fire events **MUST** be confirmed by telephoning **4444** from a hospital telephone.

ON HEARING THE ALARM

1. Stop all work. Do not continue telephone calls or collect any belongings.

2. If scanning, hit the 'emergency power down button' located to the right of the scanner control computer, and **IMMEDIATELY** remove subject from magnet.

3. Close door to the room effected by fire and close all doors as you leave the building.

4. Evacuate to the Fire Assembly point and clear people out of the work areas *en route*.

5. Do **NOT** use the lift.

6. People in workshop/console rooms should ensure that the MRI plant and patient rooms are vacated.

7. Disabled workers/visitors on floors other than the ground floor unable to use the stairs should follow their Personal Emergency Evacuation Plan or make their way to the main or rear stair well and await rescue by the fire services. For those at the rear stair well a call system is available to get help.

8. Do not re-enter the building until authorised to do so by the Fire Marshals.

MEDICAL GASES IN FIRE CONDITIONS

Gas cylinders must be kept in designated areas only. In the event of a fire, all cylinders not involved in the fire should be moved to a safe place, if possible. Make sure that before moving cylinders, valves are turned **OFF**.

Cylinders and medical gas installations should be kept as far as possible from all sources of heat and temperatures above 49°C (120°F).

Oil, grease or other combustible substances should never be used on valves, gauges, regulators or any fitting associated with medical gas cylinders or installations.

Oxygen presents particular hazards. Use of open flame or soldering equipment should be strictly prohibited if oxygen from a piped supply or cylinder is in use within 6 metres.

STORAGE OF FLAMMABLE LIQUIDS

Highly flammable liquids, when not in use shall be stored in suitable closed containers kept in a fire-resistant cabinet, cupboard or bin. If anyone is needing to store these items, please speak with Maen Bazo in the first instance (maen.bazo@ndcn.ox.ac.uk).

Magnet Safety Instructions

For anyone working in buildings
housing MRI Magnets

The MRI scanners at WIN are built around high field superconducting magnets. **The magnets are at least 50,000 times stronger than earth's magnetic field and are always on**. The following procedures must be followed at all times when working in the magnet areas.

1. The magnets are **always on**, 24 hours/day, 365 days/year; therefore, these instructions must be followed at all times.

2. The magnets are within 'Controlled Areas,' which can only be accessed by a trained operator. If you are running an experiment, the operator will give you access to the controlled area for the duration of your scanning session.

3. The biggest safety concern is the strong pull that the magnets exert on some metallic items. This includes keys, coins, scissors, wheelchairs, screwdrivers etc. No ferromagnetic item may be taken into the magnet rooms and must be left in the lockers outside the controlled area, or in the subject room.

4. Some individuals may have metal in their bodies, either because of surgery or an accident. Therefore, it is essential that anyone who enters the controlled area be screened using the Magnet Safety Screening Form.

5. All researchers must fill in a Magnet Safety Screening Form annually. If there are any changes to a researcher's condition (for example surgery or pregnancy) that could affect their suitability to enter the magnet rooms, they should not enter the controlled area, and seek advice from the radiography staff.

6. Any person, whether visitor or scanner subject, that wishes to enter the controlled area must be screened using the Magnet Safety Screening Form. The procedure is outlined in the SOP: Screening Subjects for Safety to Scan, which should be read by all those admitting someone to the controlled area.

7. In the event of an emergency around the magnet areas follow the appropriate emergency procedure (posted on the walls in the control room). Make sure that a physicist or operator has been informed – contact phone numbers are posted near the magnet rooms if the emergency is out of normal hours.

Accident Reporting Procedures

For incidents occurring at FMRIB

In the event of an emergency, the appropriate emergency services should be summoned.

- Call **2222** for emergency medical assistance
- Call **4444** in the event of a fire
- Call **4444** for the hospital security

In the case of a medical emergency or any other form of accident, however small, you should report it. Examples would include cuts, bruises, needle jabs etc. that occur as accidents or incidents within the Centre.

As a first point of call speak to one of the WIN Radiographers.

Other than for very minor incidents, an accident/incident form should be completed using the University online Health & Safety Incident Report Form: https://oxforduni-remoteforms.info-exchange.com/Incident

The senior radiographers should also be informed if staff are aware of a near-miss incident, for example where someone could have been injured or put at risk, even if no injury occurred.

Department Safety Officer: sally.franklin@ndcn.ox.ac.uk and Deputy Safety Officer: maen.bazo@ndcn.ox.ac.uk

WIN Centre Safety Reps: Jon Campbell and Michael Sanders – radiographers@win.ox.ac.uk

WIN Computing Guide

How to access the WIN Computing Resources

WIN houses advanced data processing and storage facilities, which are available to researchers working at FMRIB or OHBA.

Accounts are charged on a flat fee basis. The charges are:

£125 per month (£1500 p.a.) for a **normal account**

£17.50 per month (£210 p.a.) for a **low usage account**

In addition, should you only need to download data, free accounts are available. If you will be collecting MRI scans at the Centre you will require one of these accounts to access the data, even if you plan to analyse this elsewhere.

Low usage accounts have no access to the cluster and 10GB of storage space.

Normal accounts have full access to shared WIN cluster compute facilities plus 200GB of scratch (temporary, unbacked up) storage space and 20GB of storage space in the home directory.

There are no charges based on compute time.

New research projects involving personal data (i.e., data of a living person) should complete a Data Privacy Impact Assessment (DPIA) screening form and based on that assessment a Data Privacy Assessment (DPA) or full DPIA (see Data Security section).

Additional disk charges will be incurred for space beyond the normal account allocation in the home folder. Backed up group storage is also available for rental by group leaders at the same rate of £50 per TB per annum, pro-rata (no minimum block size). High performance, group scratch space is also available for data that does not need backup. There is no charge for scratch storage space.

Subject to appropriate DPA or DPIA approval, WIN's new high-performance computation platform hosted by the Bio-Medical Research Computing group (BMRC) is available. Full account holders may request access to the CPU and GPU compute resources housed there at no additional charge. Storage on the BMRC cluster is not included in the account fee and should be rented directly from BMRC at the research group level. BMRC storage is charged at the rate of £60 per TB per annum and has no backup so you should ideally rent additional space at WIN, copying important data to our system to protect the data.

It is a University IT statute that accounts are NOT shared, so every individual who needs access to the Centre's IT facilities will require their own account.

To obtain a WIN computing account:

1. Log-in to https://register.fmrib.ox.ac.uk/ using your Oxford username (SSO).
2. Click on update profile and fill in your details. Use the Computer Account(s) box at the top right of the page to request an account. Please make sure to enter your grant code provided by your PI. If the code is new, you will need to contact computing-help@win.ox.ac.uk to add it to the system for the first time.
3. You will be notified when your account has been set up.
4. An introduction to the computing facilities and extensive user guides are available at https://www.win.ox.ac.uk/research/it.

Display Screen Equipment Assessment

Please be aware that the use of computer equipment (Display Screen Equipment) for extended periods can result in upper limb disorders. Users are advised that frequent short breaks from their

computers, for example 5-10 minutes after 50-60 minutes of activity should be planned to reduce this risk. Online training and assessment is available at https://safety.admin.ox.ac.uk/display-screen-equipment. This site also gives details on how to arrange for eyesight tests, the cost of which, for University employees, will be met by the Department. For more information on DSE assessment, please contact your department safety officer.

Data Security

Guidance for Researchers

All data containing personal details needs to be dealt with in a responsible manner, protecting the individual's identity and complying with General Data Protection Regulation (GDPR).

The Data Protection Act 2018 requires that any personal data held is secure, accurate and relevant.

Personal Data includes **any** material that contains personal details (name, date of birth, contact details, initials etc). Within WIN, this includes paper and electronic files containing contact information, patient history or un-anonymised image data.

Data that does not contain personal details are not subject to the same restrictions, but should be handled in a careful, sensitive, and responsible manner, with care taken to avoid loss of the data.

For full and up-to-date guidance on data security visit

- https://www.infosec.ox.ac.uk
- https://researchsupport.admin.ox.ac.uk/gdpr
- https://www.win.ox.ac.uk/research/it/i-want-to/store-access-and-protect-my-data/protection

In particular you should take into consideration the advice given on the University's Data Handling pages at https://www.infosec.ox.ac.uk/handling-information which includes advice on best practice for processing and storing the various data types, including specific advice on which centrally provided cloud services may be for the different data types.

Where your research involves the handling of the personal data of a living individual consider whether it is possible to irreversibly anonymise the data prior to processing. If this is not possible (which will typically be the case with MRI images), you will be required to complete a Data Privacy Impact Assessment screening form, and depending on the outcome of this, a Data Privacy Assessment (DPA) or DPIA. A DPIA can take considerable time to complete and approve so should be carried out at the earliest opportunity. The screening, DPA and DPIA forms are available from the Compliance web site - https://compliance.admin.ox.ac.uk/data-protection-forms

Wherever possible, if full anonymisation is impossible, data should be at pseudonymised (all MRI data downloaded from WIN's scan archive facility are already pseudonymised). For details on the appropriate processes see: https://www.win.ox.ac.uk/research/it/i-want-to/store-access-and-protect-my-data/protection/anon.

Area of greatest risk

The areas of greatest risk are portable media (portable hard/SSD drive, memory stick etc) and laptops, which can easily be removed from the Centre and be lost or stolen, or data that is stored on **un-approved** cloud storage services. **The only approved synchronising cloud storage service is the Nexus 365 OneDrive or Teams services**. Your attention is also drawn to the use of imaging data within presentations (see below), which are often given outside the Centre.

Action points

- Personal Data must be kept in a secure manner that minimises the risk of loss or inappropriate access.

- Paper (including lab books, image printouts) or removable media (CDs/DVDs, memory sticks, portable drives) containing Personal Data must be appropriately filed, preferably in locked

cabinets/drawers. They must not be left lying around the Centre. Memory Stick/USB Pen drives used to store sensitive information must be encrypted to the AES128 or AES256 standards.

- Personal Data stored in computer files, excluding image data (e.g., Excel files, databases, contact details, test scores with personally identifiable content) must be encrypted at rest to an appropriate standard (see below). Efforts should be taken to avoid other users accessing such data, such as changing the access permissions (see section on encryption below).

- All image data should be pseudonymised (either converted to a form that does not store this data and named appropriately or in the case of DICOMs, have the identifiers removed from the headers using an approved anonymisation tool), and the key held either in a secure database (such as the WIN scan database) or encrypted (see below). Image files that must contain subject details (e.g., pre-processed DICOMs with full subject details) must be securely stored (physical media locked away and all files/devices encrypted).

- Consider fully anonymising data where practical (irreversibly dissociating the data from the subject's details).

- Pseudonymised data must not be stored in any way that could allow identification of the subject (e.g., by use of initials or name in the filename or folder structure).

- All Personal Data should remain within WIN approved resources as a general principle. If data needs to be removed from Centre approved resources (e.g., for analysis at home/another site), the personal details *must* be removed from the data (this includes a de-face of MRI data).

- Device backups must be encrypted to at least the same level as the source device, e.g., encrypted Time Machine or BitLocker encrypted.

Deletion of data and disposal of media

Data that are no longer needed must be disposed of in an appropriate way to ensure destruction of the personal data.

- Personal data must be deleted from hard drives when no longer used. Merely deleting the file on the disk may not be enough, traditional hard drives need to be *securely erased* or destroyed. SSDs and flash drives should be encrypted **before** first use. Backups of the data should also be considered in this process. Secure deletion from backed up WIN file stores (/vols/Data and home folders) is not possible (files will remain in the backup until the backups containing the files age out of existence) so **sensitive** data held there should be encrypted, in which case, destruction of the encryption key is sufficient to achieve this requirement.
- Paper records should be placed in the paper destruction bin located in the FMRIB building printer alcove on the first floor.
- If you have CDs/DVDs to destroy, contact admin@win.ox.ac.uk who can arrange destruction.
- Hard drives should be securely erased (see above website for details) or given to WIN IT staff for destruction when this is not possible (for example when non-functional.

Presentations

It is important that any presentations you give do not contain personal data. This particularly applies to image data that can contain personal information, either on the image itself or embedded within the DICOM header (if DICOM-based formats are used). For still and movie images of subjects/patients, a non-DICOM based file should be used (e.g., JPEG, GIF, TIF, AVI, MPEG), and created without personal data incorporated into the image.

Subject names or initials should not be used on any slides.

Where you have an audio/video recording of a living individual ensure you have written approval from the subject to its use in a public presentation. Written release forms are also required for recorded seminars and lectures from all presenters. Please see https://www.win.ox.ac.uk/about/faqs 'Can I record a talk?' for more information.

Presenter release form (for talks): https://www.win.ox.ac.uk/files/about-us/2022-23-external-presenter-release-licence-external-fv.docx

Participant release form (for group discussions): https://www.win.ox.ac.uk/files/about-us/participant-release-form.pdf

Encryption

Encryption involves the use of a unique code to disguise data, and without the code, the data are nearly impossible to decipher. It is possible to purchase devices with built-in encryption (look for FIPS 140-2 Level 3 compliance) or software can be used to achieve this. There are several packages are available freely or this may be provided as part of your computer/device standard software. Full instructions on this can be found at https://www.win.ox.ac.uk/research/it/i-want-to/store-access-and-protect-my-data/protection/encryption.

Information Security

Guidance for Administrators

In the course of your work at the university, you will handle personal data for university students and staff, as well as external visitors, collaborators, and research participants.

> 'Personal data' means any information relating to an identifiable living individual who can be identified from that data or from that data and other data.
>
> Use of personal data must comply with data privacy principles and legislation. This compliance means that personal data needs to be:
>
> - processed fairly, lawfully and in a transparent manner;
> - used only for limited, specified stated purposes and not used or disclosed in any way
> - incompatible with those purposes;
> - adequate, relevant and limited to what is necessary;
> - accurate and, where necessary, up to date;
> - not kept for longer than necessary; and
> - kept safe and secure.

Examples of these types of personal data you may be handling as an administrator include

- Bank details
- Date of Birth
- Passport Information
- Home addresses
- CV of researchers/applicants
- Grant applications
- Medical information

Examples of uses for this type of personal data include

- Taxi bookings for internal or external individuals
- Filling in, holding, or submitting expense claim forms
- Booking travel or travel insurance for internal or external individuals
- Processing or passing on CVs for job candidates or visitors
- Assisting with grant applications or gathering of information from researchers for applications

Securing information while still needed

When this data is on printed paper, do not leave paper or documents out on desks or in trays when you are not using it, particularly overnight. When not in use, please secure in a locked cabinet or drawer. Do not make unnecessary copies or give the documents to those who do not need to use the information.

When you are using personal data, you should lock your screen when you are away from your computer. If you need guidance on how to do this, please ask.

When this data is digital (email, documents on your computer), create a password for your spreadsheets or other documents, so they cannot be opened without the password. If you need help adding a password to your documents, please ask.
Please do not forward on emails or information to others who do not need it. If you do need to share files with personal data with others, you should use OneDrive through your Nexus365 account. If you need help with this, please ask.

Please note that personal data is allowed on university-owned devices only, and when the device is a laptop, it must be encrypted. If you do not know if your laptop is encrypted, please talk to the IT team.

When data is no longer needed

Once you have completed handling the data and the reason for having the data has been fully completed, you should dispose of the data.

When these forms of data are digital, you should delete the email or relevant files and documents. If you have shared any items on a cloud system (for example, OneDrive), you should remove the sharing access.

If you have printed any emails or documents with personal information, dispose of it in the secure shredding bin rather than putting it in the rubbish or recycling.

Examples of reasonable timelines for keeping personal data include
- Keeping passport and date of birth details until the trip you have booked has taken place and the individual has completed their round-trip
- Keeping candidate/visitor CVs until the job or visit has commenced
- Keeping expense forms until you know the person has been paid, or 6 months after submission of the form
- Keeping video, photo or audio recording consent forms until the media is no longer stored by the University.

If there is a problem and personal data has been disclosed or used in different way than the individual expected

If the data has been seen by or given to individuals who shouldn't see it (they aren't involved with the event/reason you have the data), it is essential you let your line manager know right away.

The situation should be reported to the Information Compliance Team (ICT): data.breach@admin.ox.ac.uk (ext. 80660/80523/16172).

The University has a legal duty to report any serious breach to the Information Commissioners Office (ICO) within **72 hours** of becoming aware of it. After you submit your report, the ICT will provide guidance and support, and decide whether the breach needs to be reported to the ICO.

Responsibility of Researchers

with respect to research ethics

1. WIN seeks to promote best practice in research ethics in all studies carried out at the Centre.
2. All scans done at WIN must be carried out with due attention to the appropriate ethical practices, whether that be CUREC or HRA/NHS ethics, or the technical development SOP.
3. The Principal Investigator who is named on the ethics application is primarily responsible for ensuring that all procedures carried out are in line with their protocol and ethical approval, and that all researchers with delegated responsibilities are appropriately trained and competent to carry out their tasks. WIN does not take on responsibility to check every detail.
4. The primary responsibility of the radiographer or scanner operator during scanning is to ensure the safe scanning of the participant. If the radiographer or scanner operator is not confident that the participant can be scanned safely, they will decline to scan the participant.
5. In line with the guidance given in the HCPC Standard of Conduct, Performance and Ethics, radiographers or scanner operators should only scan when they have seen a signed consent form for that participant and that study. In the case of scans done under the technical development SOP this would be the signature on the participant's scanning log. This is their check that some form of ethics approval and consent process has been undertaken, however it remains the researchers,' and ultimately the PI's responsibility to ensure that consent was appropriately given.
6. Recommended procedures and practices relating to MRI research can change over time, and radiographers and other centre staff are there to help with this. If current best practice changes, then researchers should ensure that these new procedures are followed and, when necessary, ethics amendments made in a timely way.
7. If any researcher or centre member is concerned that best practice in research ethics is not being followed then they would take this up, in the first instance, with the PI. If concerns remain then the issue should be raised with the Centre Director and if necessary RGEA or CUREC.
8. As well as any auditing or checks that may be carried out by RGEA, CUREC or ethics committees, the centre will periodically carry out random checks on the site file of one study to ensure that proper procedures are being carried out. This includes correct forms being used, dates being appropriate, delegate logs being up-to-date and subject paperwork being in order.

Authorship Guidelines

For WIN Researchers

WIN members often provide each other with support, training and advice and this is a very positive feature of our collective working environment. Such occasional support typically does not meet criteria for formal recognition such as co-authorship. However, there are situations in which contributions are substantial and deserve formal recognition. To ensure that credit is given appropriately, including to those that contribute "behind the scenes", WIN has guidelines on authorship principles and identifying co-authorships and acknowledgements in practice. This document deals with appropriate acknowledgement of *individuals*. It is also important to acknowledge funders and core facilities, and to cite papers describing tools or datasets being used where appropriate. Template text for acknowledgement of the WIN grant, commonly used facilities, and lists of papers describing commonly used tools, are available on the WIN intranet:

- https://www.win.ox.ac.uk/research/publications/win-authorship-guidelines
- https://www.win.ox.ac.uk/research/publications/win-authorship-guidelines/acknowledging-additional-win-support-tools-protocols-datasets
- https://www.win.ox.ac.uk/research/publications/win-affiliations-acknowledgements

General principles for authorships

Generally, an author is considered to be someone who:

- has made a substantial intellectual contribution to a published study. This could be through the design, execution, analysis or interpretation of the research AND
- has been involved in the drafting and revision of the work AND
- accepts accountability for relevant aspects of the work

These are general principles, and each journal will have its own rules for authorship. More information and guidance are available on the University of Oxford Research Integrity pages (https://researchsupport.admin.ox.ac.uk/governance/integrity/publication)

This document is intended to help WIN researchers identify when authorship might be appropriate and to ensure that potential co-authors are given the opportunity to contribute. It is good practice to have discussions about authorship early in a project and to revisit those discussions regularly, as contributions may change over time. Those who do not meet criteria for authorship but who have contributed in some way to a paper can be recognised through acknowledgements.

Guidelines for tools

At WIN, we benefit from access to shared tools such as pulse sequences, acquisition protocols and analysis software. Many of these tools are well-established and are designed to be easily used by researchers without need for direct involvement of the tool creator. We maintain a list of WIN tools, along with tool creators and any associated papers or conditions of use (link). It is important to ensure that you cite any relevant paper(s) for tools that you use, as these are also important in recognizing your colleagues' contributions.

When a new tool is made available, it is often valuable to involve the tool creator in a study making use of the tool. We encourage users to contact creators if they want to suggest collaboration on a new project. Through collaboration, the creator is given the opportunity to contribute from the planning stages and can ensure that tools are used and interpreted appropriately. Tool creators are not obliged to support researchers in this way, but most tool creators welcome this opportunity. Where the level of involvement is substantial, then co-authorship might be appropriate and should be discussed at an early stage. Tool creators or group leaders are encouraged to let WIN members know (e.g via Monday message or WIN Wednesday presentation) when a new tool becomes available.

Occasionally, direct involvement of a tool creator may be a *condition* of using a particular tool (for example if the tool is not yet at a stage where researchers could use it independently). In these cases, researchers should contact tool creators before using the tool and agree how the tool creator can support the research team in responsible use of the tool.

Guidelines for data

Researchers should only use data with appropriate permission and in line with any ethical approvals and data security rules that apply. All researchers are reminded of their responsibility to have undertaken Data Privacy and Information Security Training as per University requirements (link).

If direct arrangements (outside of WIN's open neuroimaging framework) are made for data sharing between researchers, then we recommend that the researchers discuss expectations around level of involvement and collaboration up front. Where the level of involvement is substantial, then co-authorship might be appropriate and should be discussed at an early stage. Where datasets are citable, it is good practice to include citations for any datasets used.

WIN's Open Neuroimaging project aims to make centre data, tools, and code openly available. With this system, researchers will be able to access some datasets without direct contact with the data creators. Rules and expectations around acknowledgement and authorships will be specified for each dataset.

Support from Core Centre Staff

WIN is fortunate to have some extremely experienced physics, radiography, experimental, IT and other support staff to facilitate the research of the Centre. Many studies benefit from their professional expertise and skillset, and acknowledging this help is appropriate and appreciated. We do not prescribe a form of words to put in acknowledgements, but we encourage authors to acknowledge teams, and in some cases individuals, without whom the research would not be possible. For example, scanning projects acknowledging the radiography team, and high-performance computing projects acknowledging the computing team.

Some projects benefit from significant direct involvement of a core staff member who invests specific time, expertise and intellectual input into a project. Where the level of involvement is substantial, then co-authorship might be appropriate and should be discussed at an early stage. If you are unsure as to whether it is appropriate to include a member of core staff as an author, then seek advice from your group leader or member of the WIN management board.

Guidelines for identifying co-authorships and acknowledgements in practice

At the project presentation stage (WIP meetings), researchers will be encouraged to identify any tools, approaches, or datasets they will be using that might require involvement beyond the immediate research team. This will provide an early opportunity to identify potential collaborators to bring on board at the planning stage.

It is recognised, however, that not all requirements will be captured in this way, that projects evolve over time, and that some contributions might be overlooked. We therefore want to give people the opportunity to request co-authorships when appropriate. Such requests need to be reasonable, and *final* decisions on authorships will continue to rest with any given study's senior researcher (typically the senior author on the paper).

To facilitate these requests, a paper's first author should notify all WIN members shortly before submission to the journal (minimum 2 weeks is recommended), in order to allow for any additional co-authorships to be requested. Specifically, the notification should include the paper title, author list, abstract, and acknowledgements. This should be done by emailing these details to admin@win.ox.ac.uk and we will ensure that the notification is circulated to all WIN members, within a week.

If someone has contributed to the study and feels they have been overlooked, this is their chance to discuss this with their supervisor/line-manager, who can raise this with a study's senior author if appropriate. Where a group leader is keeping a list of tools, this is their chance to raise any queries concerning contribution of the tool creator.

Announcing paper submissions in this way will require minimal extra work on the part of the paper authors, need not delay their submission, and will only require centre members and group leaders to briefly read upcoming paper titles & abstracts. This might even help raise awareness of what research is going on across the centre and increase collaboration!

Final note on externally sourced tools/data

Please be aware that some of the tools that we have available to us have been provided from external labs, for example pulse sequences and datasets. These may have licence conditions that we have signed up to and that must be observed. Typically, these conditions include the citation of papers, and the acknowledgement of individuals or groups. In certain cases they may require the inclusion of external individuals as co-authors. A summary of the most widely used licence terms is also maintained on the intranet (link).

We hope that the above guidelines will help Centre members navigate authorships and acknowledgements in a fair and transparent way.

Heidi Johansen-Berg
Director, Wellcome Centre for Integrative Neuroimaging

MRI Scanning Guide
Running Projects on the FMRIB
and OHBA scanners

Starting a new project at the WIN, particularly if you do not already have a close link, can appear daunting. However, we welcome new researchers and collaborators, and the following document is intended to help you find the right help and complete the necessary procedures as quickly and easily as possible.

Step 1 - Making Initial Contact

All studies carried out at **FMRIB** need to be signed off by the WIN Centre Director, Heidi Johansen-Berg. All studies carried out at **OHBA** need to be signed off by the Centre Director, Mark Woolrich. Please email admin@win.ox.ac.uk to make first contact about starting a new MRI project.

Step 2 – Ethics and Project Planning

As you start to plan your project, you will need to apply for ethical approval to run the project and figure out the practical details of your scanning project. These are often done in parallel, and we recommend getting in touch with WIN about both at this early stage. Before you can start your scanning project, you will be required to complete the following:

- Ethics approval
- Work In Progress Presentation
- Project Code Request Form

Please see below for more details.

A) Applying for Ethics
All projects need ethical approval prior to starting. This process involves several steps, often including approvals at the centre, department, and university level. The approval process often takes several months to complete. Please note that **you must submit your application for the WIN check before submitting it to the relevant ethics approval body**. Failure to do so may result in a delay in starting your study.

Healthy volunteer projects
If your project fits within the standard MRI approved procedure defined by CUREC, you can apply for a CUREC1 approval. Please read the MRI approved procedure on
https://researchsupport.web.ox.ac.uk/governance/ethics/resources/ap#collapse397171

If your experiment doesn't fit within the standard MRI approved procedure, it may fit under a CUREC2 application.

To complete a CUREC 1 or 2 application:
- Read the application guidance on
  https://researchsupport.web.ox.ac.uk/governance/ethics/apply/msidrec#widget-id-98531
- Download the latest template forms from the CUREC website
  (https://researchsupport.admin.ox.ac.uk/governance/ethics), enter the relevant details and make appropriate edits to the forms.

- Download and complete the WIN CUREC check sheet (https://www.win.ox.ac.uk/research/ethics/win-ethics-procedure)
- Email all documents to admin@win.ox.ac.uk who will check your application for WIN approval.
- Request your department HoD signature on the forms. This step may involve submission of project-specific risk assessments.
- Submit your forms to the Medical Sciences Division IDREC (ethics@medsci.ox.ac.uk) to receive approval.

If your study involves administering licensed drugs or other substances to healthy volunteers, you may need to use a CUREC3 application.

Patient or clinical projects
Studies involving patients or clinical work may need to use the NHS and HRA ethical approval process https://researchsupport.web.ox.ac.uk/clinical-trials-research-governance.

If you need support setting up a clinical study at WIN that is led by external collaborators, please contact laura.cini@ndcn.ox.ac.uk'

If you have questions about the ethics procedures involving MRI scans, feel free to email admin@win.ox.ac.uk.

B) Planning a Project
With many things to arrange to get your project started, you will find that making early contact with our Radiography Team is invaluable. They can help you think about practical issues to do with running your MRI project, advise on sequences and show you how to get help with stimulus presentation, recruitment, screening, and other issues. You may find it useful to start filling in a project code request form (see WIN Project Code below) at this stage, which will prompt you on several things to think about when planning your study. You can contact the Radiography Team at radiographers@win.ox.ac.uk. The team can also put you in touch with centre physicists if your MRI protocols need development.

Standard Operating Procedures
It is essential that you are familiar with the Centre's Standard Operating Procedures (SOPs), particularly in relation to **dealing with incidental findings** on participants' scans. Separate SOPs exist for adults and paediatrics, both documents are in the induction pack.

The other SOPs that may be relevant to your research are
- Screening participants for safety to scan
- Informed consent
- Ethical considerations for technical development scans
- Safety considerations for rapidly acting drugs
- MRI scanning in children aged 6-15

All SOPs are available on the WIN intranet at https://www.win.ox.ac.uk/research/ethics/sops. If you plan to use tDCS/tACS, EEG or pain devices in the scanner environment then additional procedures or training may be required. You should also consider if you need to develop any project-specific risk assessments if your project includes any additional devices or procedures.

MRI Protocol Advice
We encourage researchers to deposit their MRI protocols in the WIN Protocols Database (https://open.win.ox.ac.uk/protocols). Browsing this database can be helpful to find suitable protocols for your study. Further advice can be obtained from the Radiography team, who can also put you in touch with the core physics team as needed.

Stimulus presentation

All the scanners have computers which run stimulus presentation software. This includes PsychoPy (recommended for new projects), NBS Presentation (historically supported software at FMRIB, with extensive documentation available at www.win.ox.ac.uk/support), and Matlab (with Psychtoolbox and Cogent toolboxes) for legacy scripts. Eprime is available, but you need your own licence dongle. Alternatively, you may use your own laptop for stimulus presentation. For information and support with any aspect of stimulus presentation, physiological measurement, and custom MRI compatible instrumentation, contact the Experiment Support Team (Sebastian.Rieger@psych.ox.ac.uk; andrew.rudgewick-brown@psych.ox.ac.uk). If you are taking new equipment into the magnet room, then an equipment protocol will need to be written and its safety checked by one of the Centre staff. Template equipment protocols are at https://www.win.ox.ac.uk/research/research-facilities/3-tesla-human-mri-scanner (see links on the right-hand side under 'user guides and documents.

Equipment Purchasing and Custom Equipment
Contact the Experiment Support team early in the project planning phase if you intend to purchase any new equipment or require custom instrumentation. The team can advise on what is already available and what can be developed and built in-house, help with market research and purchasing decisions, and ensure that any new equipment will be suitable for use in our MRI suites.

Experienced researchers
Since running an MRI experiment is complex, involves risks and is expensive, it is essential that researchers are suitably experienced to deal with the participant, run the stimulus presentation and support in the case of an emergency. New DPhil students, or those new to the WIN MRI scanners, must be supervised by an experienced researcher for the first few sessions until the supervisor and the Centre staff are confident that the individual can run the study on their own. If you do not have access to an experienced researcher, please contact radiographers@win.ox.ac.uk for advice.

Analysis advice
If you have questions about how to analyse your data, then others in your research group or field with MRI experience are often an excellent place to start. If you are planning to use FSL, the Wiki has comprehensive instructions on using each of the tools (https://fsl.fmrib.ox.ac.uk/fsl/fslwiki). If you need further advice, or don't have anyone locally you can speak to, try posting your question on the FSL JISCM@IL discussion page (https://www.jiscmail.ac.uk/cgi-bin/webadmin?A0=fsl) in the first instance. If it is something not appropriate for a public forum, then a direct email to matthew.webster@ndcn.ox.ac.uk is acceptable.

Work in Progress Meetings
Any study that runs at WIN must be presented at a 'Work in Progress' meeting which are part of the WIN Wednesday meetings, 12:00-13:00. This allows others in the lab to give you valuable input into your study design, execution, and analysis. You can choose whether to present before ethics approval is sought, or after, but you will not be able to start scanning until this has been done.
To arrange to present then please visit https://www.win.ox.ac.uk/about/communications/wips.

C) WIN Project Code
A Project Code request form is available at https://www.win.ox.ac.uk/research/research-facilities/3-tesla-human-mri-scanner (link to form on the right-hand side under 'user guides and documents'). You can start filling this in at any time, as it prompts you about many of the important aspects of running your study. Once completed send the form to radiographers@win.ox.ac.uk, who will get in touch and arrange a meeting to discuss the study with you. Once the details of the study (including scan charges) have been agreed and signed off by the relevant Centre Director, the radiographers will then assign you a project code which you use to book time on the scanners.

Step 3 – Scan Costs and Charging Policy

Scan costs
Scans are billed monthly, when a list of scans completed on project codes are sent to the PI and researcher.

Researchers are charged on a 'per-scan' basis, where the appropriate charge per scan should reflect the scanner-hours required by the project including appropriate set up time. Advice on protocol durations can be obtained from the radiographers at any point, from grant proposal to pilot. Indications of the amount of scanning time that can be accommodated in sessions of various lengths are given in the table below. Note that these times are for healthy volunteer scanning using the centre stimulus equipment, studies involving patients or complex stimulus setups will likely require shorter protocols for the same scan session duration.

Scan session duration	Length of protocol
30 minutes	10 minutes
45 minutes	25 minutes
1 hour	40 minutes
1 hour 15 minutes	55 minutes
1 hour 30 minutes	70 minutes

The current per-hour rate for scans are £550/hour. Overnight scans (e.g., scanning post-mortem tissue) are charged at £1650.

If a lower scan rate was used in a grant application, or if scans are requiring more time than initially planned for, and additional funding is not available, researchers should use the 'top-up' grant scheme described below.

Budgeting for scan fees in grant applications
It is vital that researchers have sufficient funding for MRI scans in their grant proposal. To assist researchers in their grant proposals, the radiographers, with input from physicists and other centre staff, are happy to advise on estimated protocol durations to achieve the goals.

Researchers should also factor into their participant numbers some level of participant attrition.

We are aware that there are occasions when sources of funding available do not meet the full costs of scan fees and in the following instances researchers can apply to the WIN top-up grant scheme:
- Ongoing projects that were externally funded under historical (lower) rates
- Capped grants, particularly those available on early career researchers' fellowships, where the full cost of the project cannot be covered on the grant
- Ongoing projects of strategic importance that require bridging between grants

It is appreciated that it is often a considerable time between the grant submission and a project starting, and protocols may need to be lengthened in the light of recent scanning development. However, a compelling scientific case for extending the scan time without increasing the charge will need to be made using the WIN top-up grant scheme.

Please find the WIN top-up application form under the 'user guides and documents' section on https://www.win.ox.ac.uk/research/research-facilities/3-tesla-human-mri-scanner.

Failed or Partial Scans
If a full data set is not collected due to a fault of the scanner, errors by the scanner operator or failure of the shared stimulus presentation equipment then the scan will not be chargeable.

However, if researchers are using a developmental scanning method as part of their protocol, and this scan fails, then the scan will still be chargeable.

If a participant does not undertake the scan at all due to claustrophobia, not being safe to scan or similar reason then, provided the researcher has taken appropriate steps to avoid this happening (see below), the scan will not be chargeable. If a partial data set is acquired before the participant decides to withdraw then a pro-rata charge can be requested. If a scan is not completed due to the participant turning up late, not turning up at all, or cancelling at the last minute, then the full scan rate will not be chargeable, provided the researcher has taken steps to avoid this happening (see below).

Cancelled Scans
If a researcher does not turn up for a slot they have booked, then they will be charged the full scan rate for that slot. Researchers will also be charged if they cancel within 24 hours of the slot starting for a reason other than a participant cancellation or researcher illness.

If a researcher cancels a slot within 1 week of the slot starting, and another researcher does not eventually use the slot, then they may be charged the full scan rate for that slot. This is intended to reduce researchers 'blocking' slots.

If a researcher is not taking appropriate steps to avoid participants arriving late or cancelling at the last minute (see below) then these slots will be treated as a researcher 'no-show' and a full scan rate charge will be made. If a scan is not completed due to failure of researcher specific stimulus presentation equipment or the researcher not booking enough time for their requirements, then a full scan charge will be made.

When cancelling a scan on Calpendo (the scanner booking software) you should both select a reason for the cancellation **and use the cancellation text box** to explain the reason for the cancellation and any measures you took to prevent this happening e.g., confirming the scan time with the participant on more than one occasion.

Step 4 – Piloting

There are several piloting options that can be helpful when starting a new project. This includes testing new equipment or sequences and feasibility and study piloting. The radiographers will go through piloting options with you at your WIN Project Code review meeting but are happy to discuss piloting at any stage. All piloting and equipment testing bookings need to be made with the radiographers.

Sequence Development Pilots
- Some scanning can be done without CUREC ethics approval if it is for the purposes of technical development, creating/optimising or testing new sequences.
- If you think that this applies to your scanning, then read the SOP on Technical Development Scanning available from https://www.win.ox.ac.uk/research/ethics/sops.
- In the first instance you should contact the radiography team who can then put you in touch with the appropriate members of the WIN physics group.
- Scans are generally not charged and take place prior completing a WIP or submitting a WIN Project Code Request.
- Please note that the data cannot be used in your study though could be written up under the TechDev SOP.

Study Pilots
- Up to two participant pilot scans per project can be obtained without charge, although the data cannot be used in your study.

- Study pilots are useful for making sure the protocol runs correctly and that everything works as expected e.g., stimulus, paradigm, scan parameters, study specific equipment.
- Study pilots require a Calpendo code and WIN approval, they must be done under your study's ethics.
- Where appropriate, it is possible to reclassify a successful pilot as the first study scan so that the data may be used for publication, although the normal scanning fee will apply.

Feasibility Pilots
- Feasibility piloting can sometimes be helpful when there is a question about whether an experimental design will work.
- They can be done prior to the WIP taking place but require approval from either the WIN Centre Director approval (FMRIB) or OHBA Director (depending on the site).
- These scans need to be done under the studies ethics and require a Calpendo code and WIN approval.
- The scans are billed but the data can be published.

Equipment and Stimulus Testing
- Researchers can use a reasonable amount of late availability time (time not booked within 1 week of the session start) for testing stimulus presentation, setting-up or troubleshooting a protocol.
- This includes phantom scanning for equipment testing/troubleshooting with the Experimental Support team e.g., checking that a piece of equipment will respond to scanner triggers, won't produce RF noise.
- Bookings will be made under a generic testing project and will not be charged.

Step 5 – Making scanner bookings

The Calpendo Booking System
To book the scanning facilities using https://calpendo.fmrib.ox.ac.uk/bookings/ you need a WIN Project Code and a Calpendo account. Information on how to register for a Calpendo account can be found at https://www.win.ox.ac.uk/about/communications/wips/calpendo-booking-guide.

WIN Scanner Booking Policy

We have booking rules in place to maximise use of the finite radiographer covered time and ensure fair access for other studies. **Please note that a booking should only be made when a scan has been organised with a participant.** If these rules present any problems for your study design or participant group, please contact the radiographers for help.

Whether a booking is a short, medium or long-term the following always applies –

Bookings should have either the start or end of the slot adjacent to the following:
- Start of day (0900)
- QA time and radiographer break (generally 1230-1330)
- End of day (either 1645 or 1630)
- Consecutive study bookings need to have 15mins gap between them

The short, medium and long-term bookings rules are as follows -

Short-term bookings i.e. next 14 calendar days
- During busy periods there can be limits on the number of bookings that can be made.
- Any bookings cancelled within 7 days may be charged depending on the reason for the cancellation.
- Any next day bookings (including Monday bookings made on a Friday) will only be possible if there is radiographer cover. You must email the radiographers to check this before making a booking.

Medium-term bookings i.e. 2-12 weeks
- There is a limit of 4 bookings per study per week.
- The 12 week booking period will be automatically updated by Calpendo on a rolling basis.

Long-term bookings i.e. 12+ weeks in the future
- If you need to book more than 12 weeks into the future, please contact the radiographers.
- You will need to provide an acceptable reason for the booking request e.g. organising a patient participant scan on the same day as a hospital appointment.

Please note
- Where possible, please try to accommodate requests from other studies to slightly adjust existing bookings to make the best use of the covered time. In the first instance these requests should be made to the study in question and not the radiographers.
- The prep rooms (FMRIB) / changing room (OHBA) are reserved for the duration of a scanner booking and are only suitable for screening and changing the participant. If you have pre or post scan requirements you should book a testing room.
- Testing room bookings should include the study's Calpendo ID. If you do not have permission to book the testing rooms, you can request this in Calpendo.
- For FMRIB, on days were there is only one radiographer, only one scanner will be marked with availability. Bookings on the scanner without cover are possible provided there isn't a concurrent booking on the scanner showing cover. Requests to book uncovered time should be made to the radiographers.
- **Recurring scanner bookings are not allowed. When recurring bookings are cancelled, they do not generate cancellation emails notifying other users that the time has become available.**
- When emailing <radiographers@win.ox.ac.uk> please include your Calpendo ID and slot length (for booking requests).

Length of bookings
- The single biggest cause of overruns and delays is due to an insufficient amount of time being booked for a scanning session. Overruns frequently lead to lost data and acrimony between groups and studies.
- **Your scanner booking does not just cover scan time. Pre-scan screening, equipment setup, volunteer setup (explaining the session, earplug fitting, positioning, settling time if required), removing the volunteer from the scanner, equipment removal all must occur within the booked slot.**
- Especially when starting a new study, it is best to err on the side of caution when deciding on slot length. It is much easier to shorten bookings than increase them later.

Additional time for testing
- When setting up a study or in the early scans, it may be necessary to allow for a bit of extra time on the scanner. Such time can be booked by the radiographers under the TESTING project code. You are encouraged to speak to the radiographers prior to your first booking to arrange this.

Step 6 – Recruiting Participants

Initial Screening
- To avoid a scanning slot needing to be cancelled at the last minute, it is essential that you go through each of the screening questions of the entire 3T or 7T Volunteer Screening Form at the initial volunteer recruitment stage.
- Any 'yes' responses that are not covered by the scanner specific Surgery and Implant Safe List (available via https://www.win.ox.ac.uk/research/research-facilities/3-tesla-human-mri-scanner) should be checked with the radiographers via https://mail.fmrib.ox.ac.uk/mrisafety as soon as possible.
- Submitted tickets **must** follow the ticket submission instructions on the first page of the Safe List.

Please make your volunteers aware of the following –
- Attire: To ensure your comfort and safety during the scan, you will be provided with pocketless and metal-free "pyjama-style" top and trousers in various sizes. Long-sleeved tops are available.
- Attire Considerations: You may keep your underwear and socks on; however, we kindly ask you to remove underwired bras. If you have a suitable non-wired bra (excluding sports or therapeutic fabrics), you may wear this instead.
- Head Coverings: MRI Safe Hijabs are available for those who prefer or require them.
- Footwear: Disposable slippers are provided for those who prefer not to be barefoot or in socks when moving to the MRI scanner.
- Jewellery: Remove all metal jewellery, including body piercings, before the scan.
- Makeup: Avoid using eye shadow and mascara, as certain types may interact with the magnetic field. If you wish to wear eye makeup, we can provide makeup removal wipes, but please bring your own makeup for reapplication.
- Hairstyles: The way you wear your hair is important for your comfort and safety. Generally, wearing your hair down is recommended, allowing it to be laid flat under your head. Please inform the researcher in advance if you have plaits, braids, cornrows, dreadlocks, additional permanent hair weaves, or hair extensions. Large hair ties and bands are available to assist with hairstyle management in the MRI scanners.
- Women-only or men-only radiographers/scanner operators: If you would like only women or only men as your radiographers/scanner operators, please contact the researcher whose study you are participating in to request this. These requests need to be made at least a week in advance, as many of our staff work at our other locations. Please note that the researcher themself is also present at the scan.

Steps to improve participant attendance and completion
Researchers are expected to take appropriate steps to ensure participant attendance and completion. The appropriate steps will depend very much on the participant population, but examples include:
- Clear information to the participant: *Depending on the age of the participant this could be by letter or email. The date, time and location should be clear, e.g., in bold text, and clear directions to the site should be given.*
- A timely reminder: *A reminder by email or phone, a day or so before the scan session.*
- A suitable start time: *Participants should be asked to arrive suitably in advance of the scan slot. This will depend on the age and clinical condition of the participant and nature of the study. This should also allow for participants having transport or parking problems, or difficulty finding us.*
- Safety screening in advance: *Participants should be asked about their suitability to be scanned either by sending them the safety screening form or going through it on the phone.*

Step 7 – Running the Study: Researcher Preparation

Magnet Safety Reminders
- <u>Never</u> take an unscreened volunteer, visitor, or researcher into an MR Controlled Area. These are the Control Rooms, Magnet Rooms, and Equipment Rooms (NB there are a few differences with the 7T control room that we will explain to you if applicable).
- Never take a screened volunteer into a MR Controlled Area without first getting the permission of the radiographer or scan-op. This also applies if the participant has left the controlled area during a scan e.g., to go to the toilet.
- Never prop or hold open the Console/Control Room door.
- The Equipment Room door must always remain locked. If you need items from this room, you must lock the door after retrieving them.
- Never take new equipment into the Magnet Rooms without its safety having been checked (usually this will be in the form of an equipment protocol).
- Equipment that has been modified or serviced should be rechecked before being taken into the Magnet Room.

On Arrival
- When you arrive for your session it's a good idea to check in with the radiographer or scan operator to see if the current study is running on time.
- If there is a free magnet area access card, you may take one.
- Occasionally there are sensitive studies where it's critically important that there are no interruptions. If this is the case, there will be a sign advising of this on the door and we request that you respect this.
- Before starting your session, you need to make sure that you are magnet safe. You may be required to enter the magnet room at any time during your session (e.g., to explain how the button box works or in the event of an emergency).

Lockers
- Lockers are provided for volunteers <u>and researchers</u>.
- Please do not take any personal belongings or equipment into the MR Console/Control Room unless it is required for the scanning session.
- Personal belongings should be placed in the lockers when you arrive. The only exceptions to this rule are laptops and mobile phones.
- If you haven't used the card key padlocks before, one of the radiographers or scanner operators will be happy to show you how.

Use of the Testing / Preparation Rooms

- Shared facilities and a busy scanner schedule require some cooperation and flexibility to make the best use of our finite resources.
- The prep room (FMRIB) / change room (OHBA) are reserved for the duration of a scanner booking and are only suitable for screening and changing the participant. If you have pre or post scan requirements, you should book a testing room.
- The FMRIB 3T Prep Room is a dual use room. While some basic pre-scan testing can be done here, please remember that the changing cubicle may need to be used at the same time. The room can be subdivided with curtains and if they are drawn, please remember that someone may be behind them!
- When you finish using the testing/preparation room remember to take all equipment, magazines, cups etc. with you.

Stimulus Equipment and Setup
- There is detailed information on the WIN intranet on the stimulus setup and interfaces for both scanners, and the WIN Experiment Support team (sebastian.rieger@psych.ox.ac.uk and andrew.rudgewick-brown@psych.ox.ac.uk) are there to help.
- Stimulus equipment and its setup is wholly the investigator's responsibility. Talk to Experiment Support if you are not sure how to operate the equipment or if you have special requirements.
- The radiographers and scan operators' responsibilities are ensuring the safety of all those involved in the session and operating the MR systems and they cannot debug / trouble-shoot your experiment.
- The golden rule with the stimulus equipment is that you must not make any modifications and leave it as you found it. Even disconnecting a single cable from its correct port could result in days of stimulus data, and therefore scanning data, being lost (this has happened). If you need any additions or modifications to the existing setup, always consult with WIN Experiment Support first.

End of Session
- Please check that stimulus setup is returned it to its default state (this should be how you found it).
- Used scrubs need to go in the scrubs bins and the trug (bucket) should be returned to the stack.

Step 8 – Running the Study: Participant Preparation

Vision Correction
- If you are using the visual stimuli on the LCD or projector screen, please ask all volunteers if they require glasses or contact lens to see at 100cm (40 inches) for the 3T scanners and 61cm (24 inches) for the 7T.
- We have MR safe glasses and a range of corrective lenses in plus and minus dioptres. Please try to find out the participant's prescription before they attend as it can take some time to find the right combination of lenses without this knowledge (cutting into your scanning time).
- If the volunteer can wear contact lenses for the scan, it is recommended they do so.

Getting Your Participant Scan Ready
- We suggest you give your participants 10 minutes to get changed and an opportunity to go to the toilet before the scan slot.
- The scrubs come in a variety of sizes and the shelves are labelled to indicate which is which. Long sleeved scrub tops are available for those that prefer them.
- When changing participants into scrubs please ask them to remove all their own clothing apart from underpants and socks.
- MRI-Safe Hijabs are available in the scrub cupboards if required

- Disposable slippers are available for those who prefer not to be barefoot or in socks between changing and entering the scanner.
- Please also give your participant a trug (bucket) for their clothing and valuables. We suggest not locking this away until the session is ready to begin.

Pre-Scan Screening
- On the day of the scan, you need to give the volunteer another screening form to fill out.
- Volunteers must be re-screened for each attendance regardless of how recent their last scan was.
- The radiographer or scan operator will then go over the complete screening form with the participant <u>before they enter the MR Controlled Area</u>.
- This secondary check of the screening form should be done with only the radiographer or scanner operator present to maintain confidentiality.
- It is common for volunteers to omit surgeries or implants that cause them embarrassment but may contraindicate MRI.

Example Scanning Session

Bringing together all the above an example of a scanning session might look like the following -

1. Ten minutes before your booked scan time you should check in to see if scanning is running on time.
2. If so, select the appropriately sized scrubs for your participant, ask them to remove any eye make-up and change, placing their clothing and valuables into a trug.
3. Lock away the trug, suggest they use the toilet and then ask them to fill out a volunteer screening form.
4. Take the screening form to the radiographer, or scanner operator, and show them the signed study consent form. The radiographer, or scanner operator will register the participant and then screen them, on their own, in the prep room.
5. Once screened the session can begin.
6. At the end of your session, you should retrieve your volunteer's clothing and possessions.
7. Please put used scrubs into the clothing bins and the trug back with the others.
8. You should escort your participant out of the building.

Step 9 – Accessing Scan Data

Imaging Data
Access to imaging scan data requires a WIN computing account. To request an account visit https://register.fmrib.ox.ac.uk/accounts/portal/. If you do not have a SSO you can request an account by contacting Computing Help at computing-help@win.ox.ac.uk.

Image data is accessed through Calpendo via the 'My Scans' button (on the 'Projects' dropdown menu). This will take you to the Scan Retrieval webpage where the projects you are listed as a user in will appear on the left side of the page. Clicking a project will show the Scan IDs in the project and clicking on a Scan ID gives you the option to download the scan in NIFTI or DICOM format. Downloads will appear in your Jalapeno account under /vols/Data/MRdata/<username>/.

To request access to a project that you are not listed on you should use the Calpendo "Project Membership Request" button under the "Projects" menu. Once the project owner has approved the request you will be able to see the scans on the Scan Retrieval webpage.

Non-imaging Data

Access to non-imaging data e.g., raw spectroscopy TWIX files, scanner parameter PDFs, screenshots etc, will depend on which scanner you are using. NB TWIX files do not contain scan IDs so must be saved into folders or have the scan ID prepended to them.

FMRIB 3T / 7T
- Data is temporarily stored in /vols/TWIX/data
- Before you can access TWIX data you will need to contact Computing Help and tell them which projects you wish to access, and which WIN account(s) you will use.
- **Make a copy of this data, anything older than 7 days can be deleted without warning!**

OHBA 3T
- Access the TWIX folder on the Z: drive from a psychiatry networked computer and find the folder with your Calpendo ID
- You will need a password from the Experiment Support Team (Sebastian.Rieger@psych.ox.ac.uk; andrew.rudgewick-brown@psych.ox.ac.uk) to access the Z: drive initially.
- The Z: drive is intended for data transfer only (not storage), please download your data in a timely manner as it will be deleted when the drive is full.

Step 10 – End of Study

Notifying the Radiography Team
It is important that you notify the Radiography Team when you have finished the scanning component of your study. Doing do allows us to
- Send the final versions of study scanning protocol and scanning procedure, both of which are needed for using the WIN Protocol Database
- Update the project status on the WIN Calpendo to prevent you receiving unwanted automated emails about cancellations and slot availability
- Better assess demand, forward plan, and let other studies know about increased availability in scan time

MRI Scanning Service Agreement

We expect:

- To deliver a professional service to all researchers.

- To ensure that all subjects are safe to scan and to advise researches on safety issues when they are recruiting subjects.

- To provide a skilled operator to acquire scans, unless otherwise indicated on the schedule that the slot will have no scanner cover. In case of sickness or other unplanned absence, the radiographer team will endeavour to find a replacement operator, or will notify the researcher if this is not possible. The operator will be there and ready to scan for the start of the booked session, provided session is booked prior to 12 noon the previous day.

- Not to change protocols without discussing with researchers, but to highlight possible areas for improvement. If researchers request a protocol change, radiographers will indicate what the consequences will be.

- To keep all sessions to time, if necessary by cutting scans in discussion with researchers.

- To work with the researcher to keep the subject briefed and at ease, to increase the likelihood of them completing the scan.

- To communicate to researchers affected when the scanner develops a fault, and to keep researchers updated on the progress of fixing the fault.

- To check all data for quality by eye immediately after scanning and inform researchers of any issues identified.

We expect researchers:

- To be professional in interactions with radiographers and operators.

- To respect the operator's decision regarding admittance to the controlled area and the safety of scanning a subject.

- To respect the operator's decision to stop scanning if they feel that the subject needs to stop the session, and to respond to the operator's concerns about subject comfort.

- To book enough time for their scan slot, taking in to account the time necessary to set up, and if necessary make minor adjustments to equipment, and to get the subject into and out of the scanner. Researchers using particularly complex sequences or equipment, where there is an increased risk of system faults arising, should factor this in to their booking.

- To be ready to begin their experiment at the start of the booked scanning session. Should delays be unavoidable then this should be discussed with the operator as soon as possible. Subjects should be requested to arrive at for their scan well in advance of the scanning session.

- To finish their scan slot on time, by considering the possibility of cutting scans from their protocol if necessary. If delaying the subsequent scan slot is unavoidable then the researcher should discuss this with subsequent scanner users to evaluate the impact on the rest of the day.

- When a slot is unavoidably cancelled less than 24 hours in advance, to communicate this to the operator and advertise the availability of the slot using appropriate mailing lists.

- To leave shared equipment, such as stimulus presentation devices, in their default state at the end of the session, and inform the Radiography Team if they have any concerns about equipment functioning or data quality.

- To supervise new researchers, by being in the scan room, until both supervisor and Centre staff agree that the student can be approved as an 'Experienced Researcher' as defined in the 'Safe Scanning Policy'.

I have read the "WIN Scanning Service Agreement" and agree to the conditions of scanner use.

Name: _____

Signature: _____   **Date:** _____

This signature sheet should be returned to the Radiography Team

Safe Scanning Policy

For Studies on the FMRIB Scanners

For scanning at FMRIB the **minimum** number of people that must be in attendance:

Scan Type	Hours	Operator	Within Control Room	Pager holder
Category 0 Phantom Scanning	Working hours	**Trained operator**	-	-
	Extended hours and late evening	**Trained operator**	-	**Within building**
Category 1 Simple Scanning	Working hours	**Trained operator**	-	**Within building**
	Extended hours and late evening	**Trained operator**	**1 Experienced Researcher**	-
Category 1a Healthy Subjects	Working hours, extended hours, and late evening	**Trained operator**	**1 Experienced Researcher**	-
Category 2 Vulnerable Subjects	Working hours or extended hours **ONLY**	**Advanced operator**	**1 Specifically Trained Researcher**	-
Category 3 High Risk	Working hours **ONLY***	**Radiographer**	**1 Researcher plus 1 Medic/Anaesthetist**	-

Hours:

Working hours	**08:00 – 18:00 Mon-Fri**
Extended hours	**06:00 – 08:00 Mon-Fri**
	18:00 – 20:00 Mon-Fri
	08:00 – 20:00 Sat/Sun
Late Evening	**20:00 – 22:00 Mon-Fri**

*All Category 3 scans should be discussed with the Centre Director. Scanning out of hours may be permitted if appropriate cover is provided.

Scan Types:

Category 0   Phantom scanning.

Category 1   Simple scanning, with **no task fMRI** or other additional experimental manipulation, on healthy and non-vulnerable subjects.

Category 1a   Task fMRI or other additional experimental manipulation on healthy and non-vulnerable subjects. A clinical event (e.g., cardiac arrest) is not expected and the subject population doesn't require special care.

Category 2   Vulnerable subjects (e.g., very young, elderly, epilepsy, stroke, reduced mobility) or low risk intervention (e.g., simultaneous tDCS, contrast, IV drugs that do not

affect metabolism, gases) There is an increased risk of clinical event, or the subject population requires special care.

Category 3   High Risk (IV drugs that affect metabolism, anaesthetics, acutely ill subjects). There is a specific risk of clinical event.

Operators:

Trained Operator:

An operator who has completed their operator training, including yearly updating emergency evacuation training, basic life support (BLS) or higher and their scanner operator driving test.

Advanced Operator:

An operator who has significant experience in scanning subjects, is competent to deal with an emergency, as determined by the senior FMRIB staff, and has yearly updating of basic life support plus automatic defibrillation device (BLS+AED) or higher.

Radiographer: A trained radiographer who has yearly updating of basic life support plus automatic defibrillation device (BLS+AED) or higher.

Researchers:

Experienced Researcher:

A trained researcher who is competent to run their experiment. They should have had supervised experience of running MRI experiments and demonstrate safe working around the scanners. This does not include short term undergraduate or MSc project students. The Centre Director will give clarification if in doubt.

Specifically Trained Researcher:

An experienced researcher who has specific training (medical or otherwise) in the intervention being used, or in dealing with subjects from that population group, as stated in the relevant ethics application.

Medic/Anaesthetist:

A currently practicing medic or anaesthetist with appropriate honorary or substantive clinical contract with an NHS Trust and trained in Advanced Life Support (ALS).

Pager holder:

When scanning a subject alone in the control room, or scanning a phantom during extended hours, the operator must give the pager (small two-way radio handset) to a competent person who will be always within FMRIB. If the holder wishes to leave the building, they must formally hand-over the pager to another similarly qualified/responsible person who will cover in their absence e.g., lunch break.

Subject populations	
Psychiatric patients (currently remitted or well controlled)	Category 1a
Elderly (fit and well)	Category 1a
Children under 16	Category 1a
Elderly (infirm)	Category 2
Children under 12	Category 2
Using mobility aids	Category 2
Epilepsy	Category 2
Stroke or TIA	Category 2
Psychiatric patients (currently unwell)	Category 2
Neurodegeneration (dementia/PD/MND)	Category 2
Severe visual impairment	Category 2
Acutely ill	Category 3
Decreased GCS	Category 3
Haemodynamically unstable	Category 3

Experimental manipulations	
Task related fMRI	Category 1a
Monitoring or recording from devices connected to subject	Category 1a
TMS/tDCS before scanning	Category 1a
IV drugs that don't affect consciousness	Category 2
Administration of gases	Category 2
TMS/tDCS during scanning	Category 2
MR contrast	Category 2
Pain device	Category 2
Laser	Category 2
CHEPS	Category 2
IV drugs that affect consciousness	Category 3
Anaesthetics	Category 3

FMRIB Magnet Area Emergency Procedures

wellcome
centre
integrative
neuroimaging

FIRE

Turn the electrical supply OFF
'Scanner Emergency Electrical Power Down' button

Remove participant from magnet
Close magnet room door

Sound the alarm to evacuate building

Call the hospital security on 4444
State 'fire in FMRIB magnet area, adjacent to clinical MRI,
at the John Radcliffe Hospital'

Senior member of FMRIB to advise fire crew of magnet hazard

ELECTRIC SHOCK

Turn the electrical supply OFF
'Scanner Emergency Electrical Power Down' button

Shout for assistance

Call the Crash Team on 2222
State 'medical emergency FMRIB Centre, adjacent to clinical MRI'

Carry out basic life support until medical help arrives

Send someone to open secure door for emergency team

OTHER THREATS / EMERGENCIES

Call hospital security on 4444
State emergency type

OHBA_014_V1   OHBA, Department of Psychiatry
FMRIB_002_V1   FMRIB, Nuffield Department of Clinical Neurosciences
Neuro_002_V5   OCMR, Department of Cardiovascular Medicine

SOP Number   OHBA_014_V1

FMRIB_002_V5

Neuro_002_V5

SOP Title   Dealing with Research Neuroimaging Incidental Findings

	NAME	**TITLE**	**SIGNATURE**	**DATE**
Author	Martin Turner	Primary Contact Neurologist		
Author	Pieter Pretorius	Primary Contact Neuroradiologist		
Reviewer	Stuart Clare	Associate Professor, FMRIB		
Reviewer	Clare Mackay	Professor of Imaging Neuroscience		
Authoriser	Heidi Johansen-Berg	Director, FMRIB		

1.   PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to describe the procedures to be followed if, in the course of neuroimaging for research protocols, an abnormal anatomy or pathology is detected. In addition, written statements describing these procedures are provided as guidelines for inclusion in ethical applications.

2.   INTRODUCTION

All volunteers giving consent to take part in neuroimaging studies are asked to indicate that they understand the scans will not be routinely formally reported by a radiologist, and that they are designed only to be used in research. Nonetheless, in the course of scanning subjects for research protocols, abnormal anatomy or pathology may be detected by a researcher or scan operator.

The vast majority of such incidental findings require no specific action other than to inform the volunteer and their GP (so it can be noted on their medical record). However, regardless of its nature, the process of informing an individual about a possible abnormality is a highly sensitive one, that can lead to significant emotional distress if handled badly.

This document summarises the FMRIB, OCMR and OHBA policies that have been agreed to address the occasional instances of abnormal anatomy or pathology (i.e., an incidental finding) being detected as part of a University of Oxford volunteer neuro research scan. The document also describes the procedures that should be followed when an abnormal neuro research scan is detected during any of the FMRIB, OCMR or OHBA magnetic resonance imaging sessions. Finally, the document also discusses the written statements that should be included with any ethics application at the time the application is made (Appendix 1).

It should be noted that dealing with abnormal scans is an extremely sensitive issue, whether or not it has any further health implications, and needs to be dealt with in a very careful and methodical way. In particular, it is of paramount importance that the relevant research participant should not be unduly alarmed by the finding, and also that information about any subsequent interaction they may have with clinicians remains confidential and fully within their control in terms of any wider disclosure. To this end, a strict procedure (described herein) should be followed in the event that an incidental finding is noted and, importantly, the investigators/scan operators present when the scan is collected **should not** attempt to discuss anything with the participant during their scanning visit. Rather, it is necessary that the designated Contact Neurologist from whom advice is sought should form an opinion of the scan before the subject is contacted in any way about their scan.

3.   SCOPE

This SOP relates to all neuro scans performed at FMRIB, OCMR or OHBA.

4.   DEFINITIONS

PI=Principal Investigator

5.   RESPONSIBILITIES

A list of individuals currently fulfilling the following roles is maintained on the FMRIB Website.

5.1   Contact Radiographer

A senior radiographer, who coordinates the recording and referral of the incidental finding to the Contact Neurologist.

5.2   Contact Neurologist

A consultant neurologist with a local NHS contract, who, together with the Contact Neuroradiologist, determines if the incidental finding should be pursued. Discusses the finding with the participant and assumes their NHS care if necessary.

5.3   Contact Neuroradiologist

A consultant neuroradiologist with a local NHS contract, who, together with the Contact Neurologist, determines if the incidental finding should be pursued. Specifies a scan protocol for follow up scans if required.

6.   SPECIFIC PROCEDURE

6.1   Procedure for dealing with an incidental finding on an MRI scan

Note that an incidental finding may be detected either at the time the scan is collected or may be identified some time later, potentially months or even years later. Regardless, as soon as any abnormality is detected the following course of action should be followed:

6.1.1   Any scan that raises cause for concern to an investigator or scan operator should, in the first instance, be shown to the Contact Radiographer as soon as practically possible after it is noticed. The investigator can then assume that the matter is dealt with, but should not expect further feedback on outcome to protect the confidentiality of the participant (whether or not the finding is significant).

6.1.2   The Contact Radiographer will make an initial decision as to whether the abnormal finding is likely to be a scan artefact, or has already been referred. If the scan finding is determined to be artefact, or has been previously referred, then no further action will be taken, and the case will be considered closed.

6.1.3   To ensure the outcome of all cases is clear and to prevent future duplicate referrals, the Contact Radiographer will track all referrals, whether or not they are passed on to the Contact Clinician, in an anonymised password-protected database that to which only they and the Contact Clinicians have access. Only the anonymised scan number, date of scanning, and findings are recorded.

6.1.4   Once an incidental finding is suspected, the Contact Radiographer will inform the Contact Neurologist as soon as practically possible. For this purpose, the scans will be provided on CD-ROM in DICOM compliant electronic format (DICOM viewer software should be included on the CD-ROM). The CD-ROM will be labelled only with the anonymized scan number. A separate piece of paper is supplied (later securely disposed) with the name and date of birth of the participant plus the scan number to allow registration for the purposes of reporting by the Neuroradiologist. These records are NOT linked to any existing NHS records that a participant may have. It should be stressed that the participant should NOT be told anything about the referral or contacted at this point, and that the number of people involved in the overall process should be minimised.

6.1.5   The Contact Neurologist will arrange for the scans to be uploaded for viewing by the Contact Neuroradiologist. The Contact Neurologist and Contact Neuroradiologist will make a joint determination as to whether the incidental finding should be pursued, with a strong aim of avoiding participant 'harm' by only including those findings clearly known to be medically important. In the event that the incidental finding does not need to be pursued (usually a normal anatomical variant that does not need to be recorded with volunteer's GP medical records) the database will be labelled as 'no action necessary', and the case will be closed.

6.1.6   'Possibly significant' findings include those without any future consequence that nonetheless need to be recorded on a volunteer's medical record so that future healthcare professionals might know when it was first observed. This GP disclosure requires the consent of the volunteer, who must then have ultimate control over who else is informed.

6.1.7   The Contact Neurologist will ask the Contact Radiographer to obtain a method of contact (ideally telephone) to discuss the scan findings. The Contact Neurologist may offer a formal consultation and physical examination at the earliest opportunity, depending on the nature of the finding. If so, then this will be done under the auspices of the NHS in a formal outpatient clinical setting. Whether or not a formal meeting is required, as a matter of standard clinical practice, the volunteer's GP will be informed of the finding and any plan for further investigation or other recommendation in a letter from the Contact Neurologist (with the prior consent of the volunteer).

6.1.8   The nature of the finding and any further action undertaken will be added to the anonymised database.

6.1.9   The Contact Neurologist will explicitly advise all volunteers who have been contacted about their scans that it would be helpful if they let the official contact mentioned in the study's Research Ethics Committee-approved Patient Information Sheet know about the finding. Additionally, they will be advised that they should NOT take part in any future neuroimaging research without disclosing the finding to the researcher beforehand. However, any decision to disclose personal health-related information (which may be highly sensitive) RESIDES WITH THE VOLUNTEER, and there must be no attempt by any researcher to ask either the subject or the Contact Radiographer to reveal the outcome of a current or previous referral.

6.1.10   Although in some cases a researcher will be informed retrospectively by the volunteer of the outcome of an incidental finding (as advised by the Contact Neurologist), the decision on whether to remove a volunteer's scan from a study lies with the PI and must be made without the expectation of automatic disclosure by the volunteer. In theory, a PI's decision to remove a volunteer from a longitudinal study because of a significant structural abnormality risks indirect disclosure when the Contact Neurologist may not have deemed it necessary to contact the volunteer. In this rare circumstance, the PI should always inform the Contact Radiographer prior to telling a volunteer that they are being removed from further study, so that it is possible for the Contact Neurologist to make contact with the volunteer to reassure them.

```
           ┌──────────────────────┐
           │  Incidental finding  │
           └──────────────────────┘
                     ⇓
           ┌──────────────────────┐   Artefact or already   ┌──────────────────────┐
           │ Contact Radiographer │        referred         │ Contact Radiographer │
           │       informed       │          ⇒              │  updates anonymised  │
           └──────────────────────┘                         │      database        │
                                                            └──────────────────────┘
           Possibly ⇓ significant

           ┌──────────────────────┐
           │  Contact Neurologist │
           │       informed       │
           └──────────────────────┘
                     ⇓              'Not significant':
                                    i.e. no contact        ┌──────────────────────┐
           ┌──────────────────────┐  with GP needed        │  Contact Neurologist │
           │Contact Neuroradiologist│         ⇒             │  updates anonymised  │
           │       informed       │                        │      database        │
           └──────────────────────┘                        └──────────────────────┘

           Possibly ⇓ significant,
           including those that just need
           recording with GP

           ┌──────────────────────┐
           │Contact Neurologist contacts│
           │ volunteer and (with their │
           │   permission) the GP      │
           └──────────────────────┘
                     ⇓                                      ┌──────────────────────┐
                                                            │Contact Neurologist updates│
           ┌──────────────────────┐                        │  anonymised database.    │
           │Formal care passes to NHS, and│     ⇒           │ Volunteer advised that it│
           │further investigation as necessary│             │would be helpful to inform PI│
           └──────────────────────┘                        │ of outcome, and not to have│
                                                            │  further research scans   │
                                                            │    without doing so       │
                                                            └──────────────────────┘
```
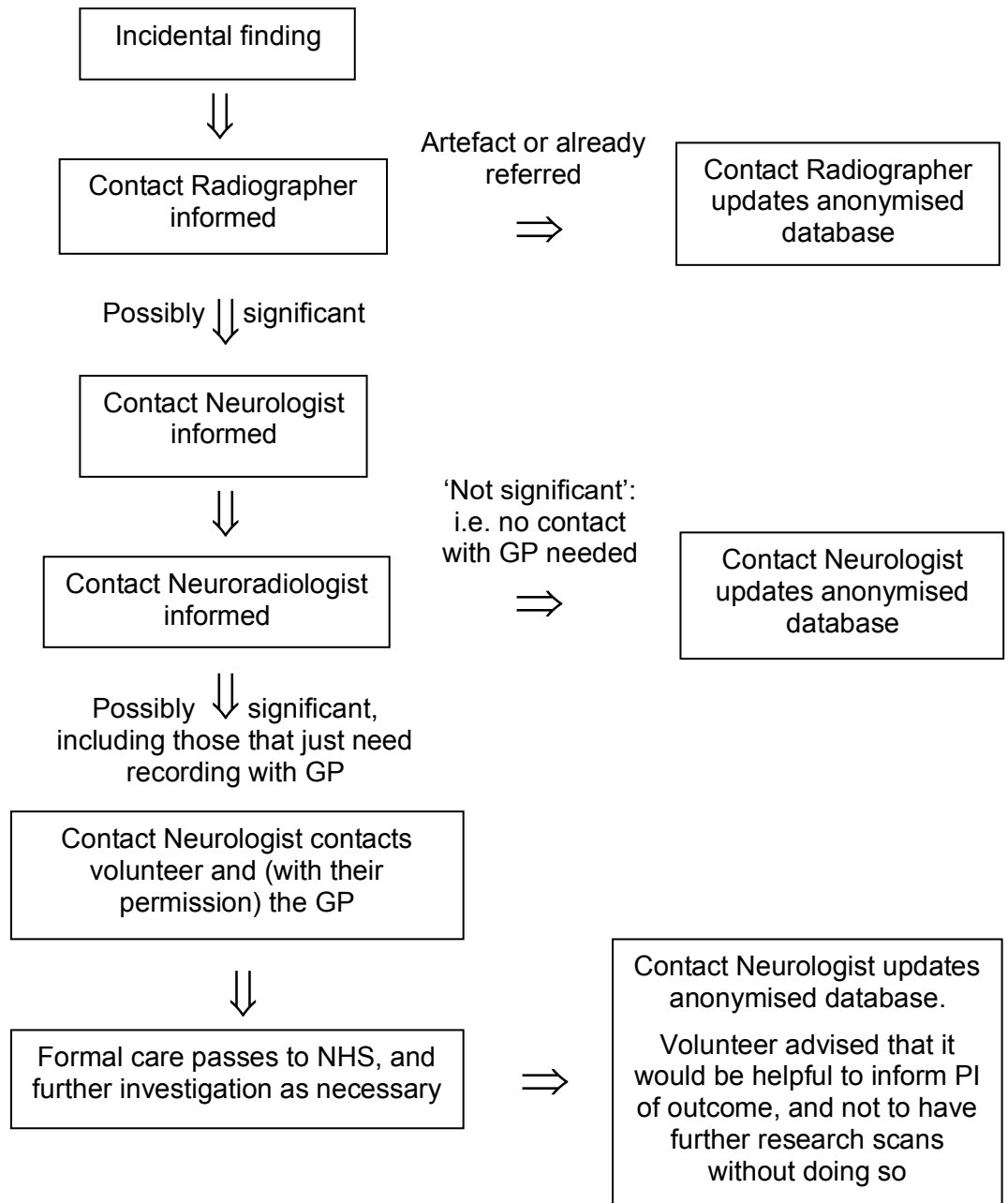
Figure1. Summary of procedures for reporting incidental findings.

7.   OUTLINE OF PROCEDURES TO BE FOLLOWED BY RESEARCHERS

If you identify a possible abnormality on a scan of any subject undergoing a scan at FMRIB, OCMR or OHBA, then:

a) Inform the PI for the project, who will then inform the Contact Radiographer

OHBA_014_V1   OHBA, Department of Psychiatry
FMRIB_002_V1   FMRIB, Nuffield Department of Clinical Neurosciences
Neuro_002_V5   OCMR, Department of Cardiovascular Medicine

b) Do NOT inform the subject of your suspicions or discuss the findings with anyone beyond the PI

c) Do NOT ask the Contact Radiographer or participant later on to reveal the outcome of any further investigation that may (or may not) have taken place

8. GUIDELINES ON VOLUNTEERS VIEWING THEIR SCANS

8.1.1 Notes on Showing Scans to Subjects

Under no circumstances should a volunteer research subject be confronted with an abnormal scan finding during their scanning visit. It is therefore recommended that subjects are not shown the images of their brains when they emerge from the scanner. Further, any promises to "show the subject their brain" should be avoided, both during volunteer recruitment and during the scan session itself. In the event that it is felt essential to show images to the volunteer, then only images that have been previewed by the scan operator should be shown.

With regard to providing subjects with images of their brain to take away, some subjects may attempt to make "diagnoses" based on their scans, and will not be able to distinguish everyday scan artefacts (signal drop out, susceptibility distortions, flow artefacts etc.) from pathology. Therefore, for many projects, it is inappropriate to provide subjects with images to take away in any form. In the cases that subjects are provided with an image of their brain then only relatively low quality laser-printer images (possibly also pseudo-colour) should ever be provided. The following text should be appended to the bottom of the images:

"These images are for illustrative purposes only. They should not be used for diagnosis."

Electronic images should **never** be provided, other than to close collaborators on the project. In the event that a volunteer requests them under the Freedom of Information Act then this request should be referred via the appropriate University channels.

8.1.2 Abnormalities Noted by Scan Operators During Volunteer Scanning

If the scan operator notes an abnormality during the scan session (i.e. when the volunteer is still in the magnet) then extreme care should be taken to avoid alarming the volunteer. The acquisition of "special" additional scans should not be attempted. Instead, the procedures referred to earlier in this document should be followed. Also, in such circumstances, it is essential that the volunteer should **not** be shown their scans.

9. GUIDELINES FOR WRITING ETHICS APPLICATIONS

When writing your ethics application, there are a number of issues that should be addressed in the documentation that relate to the potential of abnormal scan findings.

9.1.1 In the Patient Information Sheet that you write, it is recommended that the following text be included in the section titled 'Are there any risks in taking part in this study?':

It is important to note that we do not carry out scans for diagnostic purposes, and therefore these scans are not a substitute for a doctor's appointment. Our scans are not routinely looked at by a doctor, rather our scans are intended for research purposes only. Occasionally a researcher may detect a possible abnormality. In this case, we would have the scan checked by a doctor. If the doctor felt that the abnormality was medically

important, you would be contacted directly and recommended to have a hospital (NHS) diagnostic scan arranged. All information about you is kept strictly confidential.

9.1.2   In the body of the application itself the following text is recommended:

During the consent process, subjects would be informed of our standard procedure for incidental findings ("SOP – Dealing with Incidental Findings"). This outlines the process of involving a dedicated local hospital NHS consultant clinician in the case of a suspected abnormality, although it is stressed that a routine inspection and reporting of research scans is not carried out. In the case of a suspected abnormality, the Principal Investigator would alert our Contact Radiographer who, if appropriate (i.e. not a simple artefact) would independently inform the Contact Neurologist. They would in turn obtain the opinion of the Contact Neuroradiologist, and decide on the appropriate course of action, which might involve contact with the individual at the earliest opportunity and possible further investigation. This would all take place within the NHS framework and in communication with the volunteer's GP.

9.1.3   It is recommended that the following statement is included in the Consent Form itself:

"I understand that this is a research scan that is not useful for medical diagnosis, and that scans are not routinely looked at by a doctor. If a concern is raised about a possible abnormality on my scan, I will be informed if a doctor thinks it is medically important."

10.   INTERNAL AND EXTERNAL REFERENCES

University of Oxford Clinical Trials and Research Governance:

http://www.admin.ox.ac.uk/researchsupport/ctrg/classification/

WIN Web Pages

http://www.win.ox.ac.uk

OCMR Web Pages

http://www.ocmr.ox.ac.uk/internal/information-for-researchers/

11.   CHANGE HISTORY

SOP no.	Effective Date	Significant Changes	Previous SOP no.
002-V1/ Neuro_002_V1 (OCMR)	1 October 2007	Formatted to new template. Slightly amended wording on giving scans to subjects. List of named contacts moved to website. Initial contact to be by clinician not researcher.	May 2006
002-V2/ Neuro_002_V2 (OCMR)	1st June 2011	Amended wording with regard to feedback and recording of outcome in scans referred.	002-V1/ Neuro_002_V1 (OCMR)
002-V3/ Neuro_002_V3 (OCMR)	1st December 2012	Amended wording for subject information sheets.	002-V2/ Neuro_002_V2 (OCMR)
002-V4/ Neuro_002_V4 (OCMR)	2nd February 2014	Amended wording with regard to feedback to the PI from the Contact Radiographer when no contact with the GP is needed Clarification of no feedback to researchers Clarified flowchart	002-V3/ Neuro_002_V3 (OCMR)
FMRIB_002_V5 Neuro_002_V5 OHBA_014_V1	15th July 2016	OHBA added to SOP. Removed reference to supplying images as TIFF since all scanners now produce DICOM.	002-V4/ Neuro_002_V4 (OCMR)