# Guidance for Researchers

**Information on Participant Information Sheet Template – please read before starting**

The information provided to potential research participants supports the consent process and must:

* explain everything that will happen to them, should they consent to participate;
* provide the information needed for them to weigh the risks and benefits of taking part and make an informed decision for themselves;
* provide information required to meet legal and regulatory requirements

This should be done as concisely as possible without compromising clarity. It may be useful to refer the reader to other sections to avoid repetition.

This template is a guide to developing study information sheets. It has been designed with reference to HRA Participant Information Sheet Preparation Guidance (<http://www.hra-decisiontools.org.uk/consent/>) and with advice from the University of Oxford’s Information Compliance Team. It incorporates sponsor requirements, feedback from RECs, and good practice in existing sponsored research.

 Guide to the template:

* **Main headings are in bold.** Headings can remain in this format if desired. Delete or add others as relevant.
* *Instructions and explanations are in italics*.
* Example text is highlighted in blue.
If used, alter the text as relevant. Where text <to be tailored> is inserted into sample text, amend as appropriate.
* Required text is highlighted in yellow with text <to be tailored>. This includes complaints, sponsor contacts, data protection and insurance statements.
* Other documents and other sections of this document are referenced in red.

Delete all advisory text when finalising the document and remove the RGEA template information in the footer. Retain pagination.

For assistance, contact either

Oxford University – Research Governance Ethics and Assurance (rgea.sponsor@admin.ox.ac.uk ) or

Oxford University Hospitals NHS Foundation Trust – R&D (ouh.sponsorship@ouh.nhs.uk)



Insert local contact details e.g. TRUST LOGO (for multi-centre studies can be done once approval is in place)

*Add contact details of the*

*local research team and*

*either the Chief or Local Investigator*

**PARTICIPANT INFORMATION SHEET**

<Study Title>

*The title could be the same as in the protocol or a simplified version understandable to a lay person. If the latter, this should be used as the short title in the IRAS form. Titles must be consistent throughout the documentation.*

[*Invitation*](http://www.hra-decisiontools.org.uk/consent/content-sheet-invite.html#two) *paragraph: It must be clear that you are inviting potential participants to consider taking part in this research and that participation is entirely voluntary.*

Example:

We'd like to invite you to take part in our research study. Before you decide, it is important that you understand why the research is being done and what it would involve for you. Please take time to read this information, and discuss it with others if you wish. If there is anything that is not clear or if you would like more information, please ask us*.*

**Summary** or **Key Facts**

*User feedback recommends having a short summary in lay language and bullet points. Include brief description of the study, main inclusion criteria, and what is expected from participants.*

# What is the purpose of the study?

*Briefly outline of the purpose of the study in lay language. Do not cut and paste directly from the protocol.*

# Why have I been invited?

* *Explain specifically why the potential participant has been invited (e.g. because they have a specific condition, or because they are healthy individuals)*
* *State how many participants you are intending to involve and their characteristics (e.g. healthy volunteers, people with x condition). This includes participants in different stages or arms of the study, who may have a separate PIS.* Example:

The study will involve 20 patients and 10 healthcare professionals.

# Do I have to take part?

* *It must be clear that taking part is entirely voluntary.*
* *A participant can withdraw without giving a reason if they later change their mind.*
* *Make clear that neither declining to take part nor withdrawing will affect:*
	+ *clinical care (if participants are patients).*
	+ *employment or legal rights (if participants are staff members, healthy volunteers)*

# What will happen to me if I decide to take part?

* *Detail what the research study will involve for a participant: how long they will be involved; how often they will need to attend a research session; how long visits will be.*
* *Describe procedures in the order in which they will occur. If there are multiple study visits, describe them in turn. A table or flow chart can provide clarity.*
* *If research is taking place in the context of clinical care, make clear which parts are research and which are standard care.*
* *If potential participants may be screened but not enrolled, explain this clearly, stating what personal data will be collected and retained securely on screening logs. Refer them to ‘What will happen to my data’ section for legal basis and retention periods.*
* *If the study involves randomisation, describe in lay terms what this means and how it is done.*
* *If you will be collecting samples:*
	+ *Indicate amounts in lay terms.*

*For blood volume, 5ml is equivalent to 1 teaspoon; 15ml is 1 tablespoon.*

*Biopsies may be compared to grains of rice.*

* + *State whether they will be collected at the same time as clinical sampling or only for research. Add template consent form clause 4 to the consent form.*
* *If the study includes long-term monitoring/follow-up, including ‘passive’ follow-up through medical notes or data gained from central NHS registries (such as NHS England / NHS Central Register) detail the data to be collected, and frequency and duration of collection.*
* *If the study involves any ionising radiation (i.e., x-rays) or non-ionising radiation, such as MRI scans, add template consent form clause 9 to the consent form.
For MRIs, include wording from the section ‘What will happen to me if I take part?’ section in Appendix A.*

# What should I consider?

*Explain:*

* *Conditions that may exclude individuals from participation;*
* *Whether they can continue to take their regular medication or other prescribed or over-the-counter medicines;*
* *Any requirements for contraception or change of behaviour;*
* *Whether they can participate if they are involved in other research studies.*

# Are there any possible disadvantages or risks from taking part?

*Provide a fair and honest evaluation of the possible consequences of key research procedures and drugs: include risks and their relative likelihoods, as well as what you will do to mitigate these risks. These might include:*

*Procedures:*

* *MRI: add the exact wording under the section ‘Are there any possible disadvantages or risks from taking part?’ in Appendix A*
* *Blood samples: the possibility of bruising and/or fainting.*
* *Biopsies: the possibility of bruising, infection.*
* *Additional radiation when the study involves any ionising radiation: the implications of doses in addition to standard care.*
* *Questionnaires or interview questions that may cause distress: give indication of kinds of questions you will be asking, and outline what would happen if a participant became upset.*
* *Time or other demands.*

*Study Drugs:*

* *Whether the drug is commonly used for the indication being researched or for other conditions, or whether it is ‘first in man.’*
* *Known side effects. You could use a table such as:*

|  |  |
| --- | --- |
| ***Side Effect*** | ***Frequency*** |
|  | *Very common (in more than 1 in 10 participants)* |
|  | *Common (more than 1 in 100 but fewer than 1 in 10)* |
|  | *Uncommon (more than 1 in 1000 but fewer than 1 in 100)* |

# What are the possible benefits of taking part?

* *Make clear that you do not know what the outcome will be and that this is why you are conducting the research.*
* *Sometimes participants may benefit directly. If not, be equally clear that there is no benefit to them. You can add that it may help others in the future.*

# Will my General Practitioner (GP) be informed of my participation?

* *GPs should be notified if study participation could affect clinical presentation or care of participants. (GPs should be provided with a Letter and the Participant Information Sheet.)*
* *Sometimes GPs will be contacted to follow up incidental findings that may be of clinical significance, such as high blood pressure or indications of depression.*
* *If the GP will be informed of participation, make this clear and add template consent form clause 6 to the consent form.*

# Will my taking part in the study be kept confidential?

# *This is different than data section. It concerns the common law obligations of confidentiality, rather than data protection regulation.* *Since there is overlap with data processing and secure storage, it may be useful to signpost to the section, ‘What will happen to my data?’*

* *Tell participants how their confidentiality will be safeguarded during and after the study, and limits to confidentiality. The most common safeguard is use of a study/participant code. Example:*

Yes. All study records and samples will be identified only by a code. We will only use <specify: names, date of birth, NHS numbers> where this is necessary <to link to your NHS records/contact you>. Information that can identify you will only be held securely by <holder of link/ sender of reminders, information> for the purposes of the study.

* *Make clear the limits on anonymity.* Example:

Confidentiality will be maintained as far as it is possible, unless you tell us something which implies that you or someone you mention might be in significant danger of harm. In this case, we would have to inform the relevant agencies, but we would discuss it with you first.

* *Include the following text:*

Responsible members of the University of Oxford, <and> regulatory authorities <and the relevant NHS Trust(s)> may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

*There is a related mandatory template consent form clause 3. Although consent is not the legal basis for processing data in research, explicit consent is required for this access to identifiable data because confidentiality is part of common law.*

# Will I be reimbursed for taking part?

* *State whether participants will be compensated for their time or for inconvenience such as taking medication or providing samples.*
* *Make clear how these payments might be influenced by the duration of involvement in the study, including possible screening failure (if payment is pro rata) or by factors such as the completeness of diaries they provide.*
* *Make clear whether they and others who might accompany them will be reimbursed for their expenses such as: travel, meals, childcare. It should not cost participants to contribute to research; at a minimum, travel should be reimbursed. This expense may sometimes be avoided by having research visits coincide with regular clinical appointments.*
* *If compensation for time and inconvenience is substantial (hundreds of £) consider adding the following:* We will not pay tax or National Insurance from the money due to you. It is your responsibility to pay these and to check how any compensation received from taking part in the study affects any state benefits to which you are entitled. Contact HM Revenue & Customs for information (http://www.hmrc.gov.uk/ or telephone 0300 200 3300).

# What will happen to the samples I give?

* *State how samples will be used in the research, where they will be transferred or held (country, institution level), what analysis will take place.*
* *If the study involves the analysis or use of DNA, anonymising this data may not be possible. Explain this, if necessary. Example:*

To help keep your information confidential, your sample and any information recorded about you in this study will be assigned a study code that is used instead of your name or other identifiers. However, your DNA is unique to you so it can never be completely anonymous*.*

* + - *Detail plans for any samples remaining after this research has ended; whether they will be destroyed or, with consent, kept for future use.*
* *If kept for future use, ‘future-proof’ by being transparent about possible uses, as required by the Human Tissue Authority. (*[*HTA Code of Practice E – Research, paragraph 48*](https://content.hta.gov.uk/sites/default/files/2020-11/Code%20E.pdf)*)* Example:

Your samples will be used in a form that does not identify you, mainly <by local researchers> but ethically approved research projects may take place in hospitals, universities, non-profit institutions, or commercial laboratories worldwide*.* Because they will be shared in a form that does not link back to you, it will not be possible to withdraw them after they are shared.

* *Add template consent form clause 12 to the consent form. This comes after all other clauses, as it is additional to the study.*
	+ - * *To meet the traceability requirements of the Human Tissue Act, it is necessary to retain the consent form (containing personal data) until the sample has been depleted (including sharing) or destroyed. This retention may be longer than other research data is held. (see sample use consideration in ‘What will happen to my data’)*

# What will happen to my data?

* *UK General Data Protection Regulations (UK GDPR) require specifying the data controller (University of Oxford), legal basis for processing, and details of what personal data will be held by whom, for what purposes, with what security, and for how long.*
* *If the study will involve video/audio-recording, outline what will happen to recordings (which are personal data) in the longer term. If they will be transcribed, specify who will transcribe and whether the recordings will be destroyed following completion. If video or audio recording, add template consent form clause 5 to the consent form.*
* *If the study involves any automated decision-making or profiling, this must be stated.*
* *If personal data will be shared with others outside the EU, you should make potential participants aware that such countries might not offer the same level of protection of privacy as that demanded by law in the UK. Inform potential participants of the steps you will take to ensure that any such transfer of information abroad will not compromise confidentiality and obtain explicit consent for the transfer of personal data.*
* *Detailed guidance on data protection for researchers is available here:* [*https://researchsupport.admin.ox.ac.uk/sites/default/files/researchsupport/documents/media/data\_protection\_and\_research.pdf*](https://researchsupport.admin.ox.ac.uk/sites/default/files/researchsupport/documents/media/data_protection_and_research.pdf)
* *See also the University Policy on the Management of Data Supporting Research Outputs* [*https://researchdata.ox.ac.uk/policy-management-data-supporting-research-outputs*](https://researchdata.ox.ac.uk/policy-management-data-supporting-research-outputs) *and required retention periods in section 3.5. While the policy specifies a minimum retention period for research purposes, a minimum is not meaningful as a retention period for participants. Specify a set number of years in the text below.*
* *The text in this section has been agreed with University Information Compliance and is not to be substituted with Health Research Authority (HRA)\_transparency wording. The HRA has agreed to use of Data Controller wording.*

Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is ‘a task in the public interest.’ The University of Oxford is the sponsor for this study. It is the data controller, and is responsible for looking after your information and using it properly.

We will be using information from <source: e.g. you/ your hospital/GP records/ NHS England, and other central NHS registries> in order to undertake this study and will use the minimum personally-identifiable information possible.

We will store any research documents with personal information, such as consent forms, securely at the <University of Oxford> for <refer to University Policy on Management of Data; add same time period to IRAS A44/Combined Review IRAS Section B, Question 16> after the end of the study, <*indicate study duration, for context*> as part of the research record.

*If study involves MRI scanning also add the following:*

<Authorised MRI scanning centre personnel at [please add name of imaging centre here] and the research team will have access to the MRI imaging data. MRI imaging data is assigned a unique ID as it is collected, and stored in a secure database on University managed IT systems. Due to the nature of the MRI images, they remain potentially identifiable, even after we destroy your personal details. Imaging data will be stored on archive tapes at the MRI location and kept indefinitely, for quality control, and to facilitate further use of the scans where permission has been given. >

<If you agree to your samples being used in future research, your consent form will be held securely until the samples have been used up.>

<If you agree to your details being held to be contacted regarding future research, we will retain a copy of your consent form securely until such time as your details are removed from our database. We will keep the consent form and your details separate from one another and any research data.>

*Include if there is payment via bank transfer:*

<Your bank details will be stored for 7 years in accordance with University of Oxford financial policy.>

*Include in all cases:*

We will keep any other identifiable information about you for <specify, considering whether contact details need to be retained to send study summary; add same time period to IRAS A43/Combined Review IRAS Section B Question 15> after the study has finished.

* *If there is a* ***site*** *processing details also add the following:*

The <local NHS Trust or local study team> will use your <list details, e.g. name, NHS number, home address, and contact details>, to <give reason: e.g. contact you about the research study, and to oversee the quality of the study>.

* + *If participant is a patient at the site, add:*

A copy of the consent form from this study will be kept in your medical records for as long as those records are retained.

* + If the site is contacting participants, add:

They will keep any other identifiable information about you from this study for <time as per previous paragraph/IRAS43/Combined Review IRAS Section B Question 15> after the study has finished.

* *Details about any third-party processors such as apps, cloud servers, mailing services and transcriptionists, must be provided, including their specific role, retention periods of data, and relevant security measures. Where relevant, there will have been referral to the University’s Information Security for Third Party Security Assessment (TPSA):* *grc@infosec.ox.ac.uk*

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at <https://compliance.web.ox.ac.uk/individual-rights>

You can find out more about how we use your information by contacting <CI or study team email>.

# What will happen if I don't want to carry on with the study?

* *Refer to ‘Do I have to take part?’ and/or reiterate that:*
	+ *Participation is voluntary: participants may change their minds at a later stage.*
	+ *Withdrawal will not affect the care they receive from any relevant service (e.g. for patients, from the NHS).*
* *Detail procedures for withdrawal*
	+ *Are there any safety implications? Will participant be followed up and a final visit arranged?*
	+ *Will samples and data collected to point of withdrawal be retained for the study, removed, or will the participant have a choice? If data is being collected in a form that does not identify them, note that it will not be possible to withdraw their data.*
	+ *If the study intends to retain tissue or data for future research, specify the effect, if any, of withdrawal on consent given for future use.*

Examples:

If you withdraw from the study, we will destroy all your identifiable samples, but will use the data collected up to your withdrawal. (*This is an example of how a participant’s data rights may be ‘limited’) o*r:

If you withdraw from the study, unless you state otherwise, any blood or tissue samples collected to that point will be used for research as detailed in this participant information sheet. You are free to request that your blood or tissue samples are destroyed.

# What will happen to the results of this study? or What happens at the end of the study?

* *Reassure potential participants that they will not be identified from any report or publication placed in the public domain. If they will be (for instance, with images of faces) it will be necessary to obtain specific consent for this.*
* *Inform potential participants of plans to:*
	+ *Publish research findings;*
	+ *Present findings at conferences;*
	+ *Feed back findings to participants themselves. Will you provide them with a summary (requires retaining their contact details), add in a link to a website from which they could get the information, or ask them to contact you?*
	+ *Share with other researchers in a form that does not identify the participant.*
* *State whether the study is part of an educational project, such as fulfilment of requirements for a DPhil.* Example:

Some of the research being undertaken will also contribute to the fulfilment of an educational requirement (e.g. a doctoral thesis).

# What if we find something unexpected?

* *Consider whether analysis of images, samples, or questionnaire responses might produce findings of clinical significance for participants or (in cases of some genetic analysis) their relatives.*
* *If so, specify the management pathway of these incidental findings. Research procedures are not a substitute for clinical investigation: management will typically involve clinical verification and/or referral to the participant’s GP.*

# What if there is a problem?

Example:

If you have a concern about any aspect of this study, please speak with <the clinical/research team>. They will do their best to answer your questions.

*Mandatory statement provided by the University Risk and Insurance Manager:*

The investigators recognise the important contribution that volunteers make to medical research, and will make every effort to ensure your safety and wellbeing. The University of Oxford, as the research sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your taking part in this study. If something does go wrong, you are harmed during the research, and this is due to someone's negligence, then you may have grounds for a legal action for compensation. While the Sponsor will cooperate with any claim, you may wish to seek independent legal advice to ensure that you are properly represented in pursuing any complaint. The study doctor can advise you of further clinical action and refer you to a doctor within the NHS for treatment, if necessary.

*If the study includes a clinical procedure, add:*

NHS indemnity operates in respect of the clinical treatment provided.

*Add investigator contact details to the following mandatory statement (the CI has overall responsibility for the study):*

If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this study, contact <name of investigator><contact details (phone number & email)> or you may contact University of Oxford Research Governance, Ethics & Assurance (RGEA) at rgea.complaints@admin.ox.ac.uk or on 01865 616480.

*If the study involves any procedures that would be part of a patient’s standard care, include:*

The Patient Advisory Liaison Service (PALS) is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. PALS is unable to provide information about this research study.

If you wish to contact the PALS team please contact <insert relevant NHS site phone number and email from the PALS website http://www.ouh.nhs.uk/patient-guide/pals.aspx>.

# How have patients and the public been involved in this study?

* *Patient and public involvement (PPI) is increasingly encouraged by funders and regulators and*  [*Health Research Authority (hra.nhs.uk)*](https://www.hra.nhs.uk/planning-and-improving-research/research-planning/participant-information-quality-standards/) *as part of Participant Information Quality Standards.* *Potential participants may have greater confidence to take part if they know that patients or the public have been involved in planning the study. Guidance and resources are available at* <https://www.nihr.ac.uk/documents/ppi-patient-and-public-involvement-resources-for-applicants-to-nihr-research-programmes/23437>

Examples:

Service users helped develop the research topic and what research questions should be asked and will continue to be involved in the study.

Potential participants were involved in reviewing this Participant Information Sheet.

In designing this study, we have received patient advice on the frequency of participant visits and the tests that we will carry out.

Potential participants were involved in describing the inclusion and exclusion criteria for this study.

*It may be useful to include one or both of the following links to general information about taking part in research:*

* www.crn.nihr.ac.uk/can-help/patients-carers-public/how-to-take-part-in-a-study/
* www.nhs.uk/Conditions/Clinical-trials/Pages/Introduction.aspx

# Who is organising and funding the study?

* *State that the University of Oxford is sponsoring the study. List the CI and other who are organising, and name the funders.*
* *State whether a potential participant’s doctor is being paid for their role in the study* Examples:

Researchers will pay (name of hospital department or research fund) for including you in this study. Or

Your doctor will be paid for including you in this study.

* *Specify any competing interests, naming who holds the interest and what safeguards are in place, if relevant.*

# Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants’ interests. This study has been reviewed and given a favourable opinion by < \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_> Research Ethics Committee.

# Participation in future research:

*Include this section if you will seek consent from participants to approach them about other research in future.*

* *State that all contact will come from the research team of this study in the first instance, that agreeing to be contacted does not oblige them to take part in future research, and they can be removed from this register at any time they wish.*
* *Detail where and how their contact details will be held.* Example:

Your contact details would be held securely, separately from this study on <describe arrangements – eg, a password protected computer in the Department of XY accessible by (specify role from this study/authorised individuals)>

*Add template consent form point 11 to the consent form.*

# Further information and contact details:

Please contact < > by < >(telephone, e-mail, in writing)

*Thank you for reading this information.*

*or*

*Thank you for considering taking part.*

# APPENDIX A:

**Text for studies involving MRI scanning**

*The following statement was designed in collaboration with Oxford Centre for Functional Magnetic Resonance Imaging of the Brain (FMRIB). If you are intending to use MRI scanning, consider adding this wording.*

*Text to add to the section,* ***What will happen to me if I take part?***

[*Please ensure any pre-screening visits/procedures are detailed in the body of the PIS if there are multiple visits*].

A researcher will *contact you / meet you* to go over the information sheet, explain what you would need to do, and go through a screening form with you to check if it is safe for you to participate. If you are suitable and agree, we would ask you to come to the **[please add name of imaging centre here?]** for the study scan**.** Before you come to your visitplease let us know if you wear contact lenses or glasses

On arrival, one of our research team would meet you to review what participation will involve and answer any questions you may have. If you are happy to continue, they will then ask you to sign a consent form. Someone will go through the MRI Screening Form with you again to make sure that it is still safe for you to take part.

You would be asked to lie still on a table inside the MRI scanner while having a series of MRI scans over a period of [*insert duration*] minutes. The entire research visit will last for up to [*insert duration*] hours. If someone comes with you, the research team can show them to an area where they can wait.

*Example text for scan and additional procedures, as relevant:*

**Before** the scan, you would *[insert specific detail e.g. computer-based or paper and pencil tests in a separate room].*

**During** the scan you would [*insert specific detail e.g. be asked to make particular movements, to respond to specific stimuli (for example, a sound, something presented on a screen, or a touch) or to perform simple thinking tests.*]  You would wear a respiration belt (which goes around your chest) to measure your breathing rate and a finger clip to monitor your blood flow.

**After** the scan, you would [*insert specific detail e.g. complete questionnaires asking about your lifestyle, experiences, or mood*].

**Text to add to section, Are there any disadvantages or risks in taking part?**

MRI is safe and does not involve any ionising radiation (x-rays). However, because it uses a large magnet to work, MRI scans are not suitable for everybody. You would be asked to answer some safety questions to determine if you can take part. Normally, we would need more information before you take part in the research MRI scan if you have a heart pacemaker or stent, mechanical heart valve, mechanical implants such as an aneurysm clip, joint replacement (e.g. hip/knee), or if you carry other pieces of metal that have accidentally entered your body.

While there is no evidence that MRI is harmful to unborn babies, as a precaution, the Department of Health advises against scanning pregnant women unless there is a clinical benefit.  We do not test for pregnancy as routine so if you think you may be pregnant you should not take part in this study.

While very rare, tattoos can occasionally warm up in the scanner. Please inform the person operating the scanner immediately if you feel any heating. If you have a new tattoo, you should not take part in a scan until 48 hours after receiving the tattoo.

If you think you might be claustrophobic, please talk to the researcher in advance, or let the person operating the scanner know before you start.

Some of the scans are noisy, so we will give you earplugs to make this quieter for you. It is important that these are fitted correctly, as they are designed to protect your hearing.

In preparation for your scan and for your comfort and safety we may ask you to change into scrubs ("pyjama-style" top and trousers), available in a range of sizes. You may keep your underwear and socks on, but you will need to remove underwire bras. If you have a suitable non-wired bra you may wear this instead. Do not wear any fabrics that contain metallic threads or are silver impregnated (often marketed as anti-microbial/bacterial or anti-odour/stink). Metal jewellery, including body piercing, must also be removed. If you wish to wear eye makeup to your scan, we will give you makeup removal wipes because you should not wear eye shadow or mascara in the scanner. If you wish, bring your own makeup to reapply. Lockers are provided to secure your personal belongings and clothing.

[For 7T studies - Some people scanned in MRI scanners, especially 7 Tesla scanners, may experience a mild dizzy sensation as they are moved into the scanner. This is normal and the sensation starts to go away as soon as you are in the scanner.]

You will be introduced to the scanner carefully and allowed to leave at any stage. Whilst in the scanner you will have a call button, which you can press if you need to stop the scan or speak with the person operating the scanner.

It is important to note that we do not carry out scans for diagnostic purposes, only for research.. . Our scans are not routinely looked at by a doctor and are therefore not a substitute for a doctor’s appointment. . Occasionally, however, a possible abnormality may be detected. 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 further assessment arranged as necessary. You would not be informed unless the doctor considers the finding has clear implications for your current or future health. All information about you is kept strictly confidential.

Add to **What will happen to my data?**

Authorised scanning centre personnel and the research team will have access to the MRI imaging data. MRI imaging data is assigned a unique ID as it is collected, and stored in a secure database on University managed IT systems. Due to the nature of these images, they remain potentially identifiable, even after we destroy your personal details. Imaging data will be stored on archive tapes indefinitely, even if you withdraw from this research.