**Sponsor Template 3: Participant Information Sheet Template**

This document should be used in conjunction with:

* SPONSOR GUI 15 Participant Information Sheet Template Associated Guidance
* SPONSOR GUI 14: Preparation of Participant Information Sheets and Informed Consent Forms

This template is a guide to developing study information sheets. It incorporates advice and guidance from: the HRA (<http://www.hra-decisiontools.org.uk/consent/>), the University of Oxford Information Compliance Team (ICT), Legal Services Office (LSO), good practice in sponsored research, feedback from NHS RECs and sponsor requirements.

Study information provided to potential research participants supports the consent process. The PIS must:

* explain what will happen to participants should they consent to participate
* provide participants with the information needed to weigh the risks and benefits of taking part and make an informed decision
* provide information required to meet legal and regulatory requirements.

Be concise without compromising clarity. Refer the reader to other sections to avoid repetition.

**TEMPLATE GUIDE:**

* **Main headings are in bold.** Delete or add others as relevant.
* *Suggested and recommended text is in italics. These can be used verbatim or adapted as required. Where [blue text in square brackets] is inserted into recommended text, amend as appropriate.*
* Mandatory text is highlighted in yellow
* Items highlighted in blue must be added to the consent form
* **The GDPR transparency statement must not be altered in any way** except for the information in **[**blue text in square brackets**]**
* Other guidance documents and policies are referenced in red.

When finalising the document please:

* Delete all advisory text and instructions intended for research teams
* Remove RGEA template information in the footer
* Retain pagination.



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]

**Invitation paragraph**

Please refer to SPON GUI 15 Participant Information Sheet Template Associated Guidance

Explain that the participant is being asked to take part in the study and that participation is voluntary. You can use the following paragraph:

*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.*

State if a translation of the participant information sheet can be made available and how the participant may request this. You could adapt or use the sentence below:

*If you need a copy of this information sheet in another language, please ask* ***[****insert contact name/study team member who will arrange/provide the translation****]***

**Purpose of the study**

Please refer to SPON GUI 15 Participant Information Sheet Template Associated Guidance.

Include a **brief** description of what the study is about in lay language.

# Why have I been invited?

Explain:

* why the potential participant has been chosen (e.g. specific condition, healthy volunteer)
* how many participants you intend to involve and their characteristics - including participants in other arms of the study (and those who may receive a different PIS) e.g. This study involves 10 patients and 10 healthcare professionals.

# Do I have to take part?

Explain that taking part in the study is entirely voluntary. The following paragraph can be used/adapted:

*It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are free to withdraw at any time and without giving a reason. Withdrawing from the study will not affect the healthcare you receive or your legal rights.*

# What will happen to me if I decide to take part? Please refer to SPON GUI 15 Participant Information Sheet Template Associated Guidance

Include:

* What the study will involve for the participant including a description of the procedures, the order in which they will occur, whether multiple study visits are required and what will happen at each visit
* How long the participant will be involved in the research
* How often they will need to attend a research session/clinic
* How long research visits will last for
* Clear description of procedures/activities that are part of standard care and those that are research (for studies taking place in clinical care)
* A lay description of what randomisation means and how it will be done (where applicable)
* A statement that some participants may be screened but not enrolled in the study (where applicable)
* A description of the personal data that will be collected and retained on screening logs (cross reference to the “What will happen to my data” section).

Studies collecting samples should include:

* an indication of the amounts to be collected in lay terms
* State if sample/s will be collected at the same time as clinical sampling or for research purposes only
* Add template consent form clause 4 to consent form.

Studies that involve 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) should:

* Include a description of the data to be collected
* State the frequency & duration of collection.

Studies involving **ionising radiation** (e.g. x-rays) or **non-ionising radiation** (e.g. MRI scans):

* Studies involving MRI scans should include the relevant mandatory text
* Add template consent form clause 9 to the consent form.

**What should I consider?**

Explain:

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

**Are there any possible disadvantages and risks of taking part?**

Please refer to SPON GUI 15 Participant Information Sheet Template Associated Guidance

Provide a fair and honest evaluation of the possible consequences of key research procedures and drugs. Describe the risks and their relative likelihoods and the mitigations in place to reduce these.

Risks and disadvantages may include:

|  |  |
| --- | --- |
| Blood samples | possibility of bruising and/or fainting |
| Biopsies | possibility of bruising and infection |
| Additional radiation | implications of doses received in addition to standard care |
| Questionnaires/ interview questions | Potential for distress (indicate the kinds of questions you will be asking, describe process for managing participant distress) |
| Time or other demands |  |

Study drugs – state:

* 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 (see guidance for presenting this information clearly)

Studies involving MRI scans must include the wording below:

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). 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.

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.

Studies involving 7T scanning must add:

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.

**What are the possible benefits of taking part?**

Explain that the outcome of the research is not known yet and that is why you are conducting the research. Some participants may benefit directly and/or it may help others in the future. Be clear if there will be no benefit to participants.

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

Please refer to SPON GUI 15 Participant Information Sheet Template Associated Guidance

State if the participant’s GP will be notified. If notifying GPs:

* Include the letter to the GP in the document set for sponsorship review
* Add template consent form clause 6 to the consent form.

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

Explain how participants’ confidentiality will be safeguarded during and after the study. The most common safeguard is use of a study/participant code.

You could use the following paragraph below:

*Yes. All study records and samples will be identified only by a code. We will only use* ***[****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.*

Explain limits on anonymity. You could use the following paragraph:

*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.*

The following text must be included:

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.

* Add template consent form clause 3 to the consent form

# Will I be reimbursed for taking part?

It should not cost participants to contribute to research.

Explain:

* whether participants will be compensated for their time or for inconvenience
* how payments may be influenced by the duration of involvement in the study
* whether participants and those who might accompany them will be reimbursed for expenses such as travel, meals, childcare etc.

If compensation for time and inconvenience is substantial (hundreds of pounds), include the following mandatory text:

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)
* how they will be analysed
* plans for any samples remaining after this research has ended (whether they will be destroyed or with consent, kept for future use)
* add template consent form clause 12 to the consent form (after all other clauses as it is additional to the study).

Samples retained for future use:

Explain the possible uses of these samples, including commercial use as required by the Human Tissue Authority (HTA Code of Practice E – Research, paragraph 48). You could use the following paragraph:

*Your samples will be used in a form that does not identify you, mainly [by research team] but also ethically approved research projects which 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.*

Studies involving the analysis or use of DNA:

Anonymising this data may not be possible. You could use the following paragraph:

*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 and other identifiers. However, your DNA is unique to you so it can never be completely anonymous.*

**What will happen to my data?**

Please refer to SPON GUI 15 Participant Information Sheet Template Associated Guidance

**before** completing this section

The following text has been agreed as the **University’s GDPR transparency statement** and has been registered with and approved by the Health Research Authority (HRA). **This wording should not be amended or altered** except where it is necessary to include additional detail requested in square brackets **[ ]** and should not be substituted with the HRA transparency wording.

Wording in black text should not be altered

Wording in **[blue text in square brackets]** should be amended to suit study specific arrangements/circumstances.

Options/instructions in red should be deleted once applied.

Data protection legislation requires that we, the University of Oxford (whose legal name is The Chancellor Masters and Scholars of the University of Oxford), 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 and is responsible for looking after your information and using it properly.

We will need to use information from you **[**from your medical records/your GP/your hospital records etc.**]** for this research project. We will share your information related to this research project with the following types of organisations **[**insert organisation types**].**

This information will include your **[**initials/ NHS number/ name/ contact details/ provide a bullet list of identifiers held for the research**]**.

People will use this information to do the research or to check your records to make sure that the research is being done properly.

**OPTION where applicable:** People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

**OPTION if not already stated:** We will keep all information about you safe and secure by: **[**include a bullet list of some steps you will take to keep information secure**]**.

***International Transfers***

Please choose the option that applies to your study.

NB: If choosing Option 1, please ensure that you have checked whether any third-party service providers involved in the study are based outside of the UK. If Option 1 is selected, new consent would be required to make any such transfers in the future (including to service providers).

**OPTION 1 NO transfers out of the UK** – please use the wording below:

Your personal data will not be shared outside the UK.

**OPTION 2 If transfers out of the UK** **WILL OCCUR –** including if this remains a possibility in the future AND if this includes sharing data in de-identified form with other researchers **–** please use the following wording:

We may share data about you outside the UK for research related purposes to:   
**[**In bullet points, concisely list the reasons why you will send data out of the UK**]**

If this happens, we will only share the data that is needed. We will also make sure you can’t be identified from the data that is shared where possible. This may not be possible under certain circumstances – for instance, if you have a rare illness, it may still be possible to identify you. If your data is shared outside the UK, it will be with the following sorts of organisations: **[**insert list**]**.

We will make sure your data is protected. Anyone who accesses your data outside the UK must do what we tell them so that your data has a similar level of protection as it does under UK law. We will make sure your data is safe outside the UK by doing the following:

* (some of) the countries your data will be shared with have an adequacy decision in place. This means that we know their laws offer a similar level of protection to data protection laws in the UK
* we use specific contracts approved for use in the UK which give personal data the same level of protection it has in the UK. For further details <https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/international-transfers/>
* we do not allow those who access your data outside the UK to use it for anything other than what our written contract with them says
* we need other organisations to have appropriate security measures to protect your data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect your data against accidental loss and unauthorised access, use, changes or sharing
* we have procedures in place to deal with any suspected personal data breach.  We will tell you and applicable regulators when there has been a breach of your personal data when we legally have to. For further details about UK breach reporting rules <https://ico.org.uk/for-organisations/report-a-breach>.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

We will keep your study data for the minimum period of time required by **[**refer to University Policy on Management of Data for minimum periods**]**.

*What are your choices about how your information is used?*

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. You have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.  
 **OPTION if follow up data will be collected after withdrawal:** If you choose to stop taking part in the study, we would like to continue collecting information about your health from **[**central NHS records / your hospital / your GP**]**. If you do not want this to happen, tell us and we will stop.  
  
**OPTION if data will be used for future research:** If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study. **[**Insert details of any specific bank / repository**]**

You can find out more about how we use your information, including the specific mechanism used by us when transferring your personal data out of the UK by:

* asking one of the research team **[**include CI or study team email**]**
* sending an email to **[**relevant email contact**]**
* calling us on **[**study team number**]**
* contacting the University’s Data Protection Officer [data.protection@admin.ox.ac.uk](mailto:)
* looking at the University’s privacy notice available at: <https://compliance.admin.ox.ac.uk/research-data>.

If you would like to find out more about the use of confidential data in research, the HRA has developed a general information leaflet which is available at: <https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/template-wording-for-generic-information-document/>.

**GDPR Wording for use in a SUMMARY PIS only (please note this summary wording CANNOT be used for the full-form PIS):**

In this research study we will use information from **[**you**]** **[**your medical records**] [**your GP**] [OTHER]**. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study.

Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules.

At the end of the study we will save some of the data **[**in case we need to check it**]** **AND/OR** **[**for future research**]**. We will make sure no-one can work out who you are from the reports we write.

The information pack tells you more about this.

Studies involving third-party service providers or subcontractors must include the following text:

We may use third party service providers or subcontractors to help with some of the research activities we carry out (e.g. IT provision, survey provision, transcription services etc.). We may therefore share your personal data with these providers when it is necessary to do so to allow them to carry out the services we require them to provide. However, we require all our third-party providers to have appropriate security measures in place to protect your data and we only allow them to process your data for the specific purposes we have stated in our instructions.

Studies involving MRI scanning must 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.

Studies involving payments via bank transfer must add:

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

If there is a site processing details 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 the 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 1**]** after the study has finished.

If the study involves video/ audio-recording explain:

* Outline what will happen to the recordings after transcription
* Specify who will transcribe the recordings
* Include the statement on Third Party Providers
* Add template consent form clause 5 to the consent form

If the study involves any automated decision-making or profiling, this must be stated.

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

Explain how participants can withdraw from the study including:

* any safety implications and mitigations in place to address these (e.g. will there be a follow-up and final visit arranged)
* what will happen to blood or tissue samples collected up to the point of withdrawal including whether data and tissue collected until the point of withdrawal will be retained, removed or the participant given a choice.
* If data is being collected in a form that does not identify participants state that it will not be possible to withdraw their data.
* State the effect, if any, of withdrawal on consent given for future use of tissue and data.

You could use or adapt the following statements:

*You can change your mind at any time. If you withdraw from the study, we will destroy all your identifiable samples, but will continue to the use the data collected up to your withdrawal.*

Or

*You can change your mind at any time. 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?

Explain:

* plans to publish research findings and present at conferences
* when results are likely to be published
* how participants may obtain a copy of the results/findings (via summary, a link to a website, requesting them from the research team?)
* that participants will not be identifiable from any report or publication placed in the public domain
* whether the study is part of an educational project such as the fulfilment of requirements for a DPhil. You can use this sentence:

*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?

Please refer to SPON GUI 15 Participant Information Sheet Template Associated Guidance

State if the 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 this applies, clearly describe:

* what will happen if any incidental findings are discovered
* the reporting mechanism and procedure for these (management will typically involve clinical verification and/or referral to the participant’s GP).

# What if there is a problem?

This section explains what will happen if the participant wishes to raise a concern or complaint. You could use the sentence below:

*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 of complaints procedure (NB 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](mailto:rgea.complaints@admin.ox.ac.uk)

Mandatory statement required by University Risk and Insurance:

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.

Studies involving any procedures that are part of a patient’s standard care must add:

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**]**.

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

Explain what public involvement has been carried out. You could adapt/include some of the following:

Patient and Public Involvement was involved to develop [the research topic/study design/participant materials/questionnaires] 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 a link to general information about taking part in research:

* <https://www.nihr.ac.uk/get-involved/public-involvement>
* <https://www.hra.nhs.uk/planning-and-improving-research/best-practice/public-involvement/public-involvement-newsletter/>

# Who is organising and funding the study?

Include the following:

* a statement that the University of Oxford is sponsoring the study
* Name all the funders
* List the CI and other collaborators who are organising the study
* State whether a potential participant’s doctor is being paid for their role in the study. You could use the following examples:
  + *Your doctor will be paid for including you in this study*
  + *Researchers will pay* ***[****name of hospital department or research fund****]*** *for including you in this study.*

**Conflicts of Interest**

* State any competing interests, naming who holds the interest and what safeguards are in place if relevant.
* Name any investigators who are shareholders and/or employees and/or Board members of a company/funder/manufacturer/device/drug etc. related to the study
* Explain the mitigations in place to ensure any conflicts of interest will not impact the study, in particular how participants are recruited/consented, how data is analysed or patient safety assessments. This could be done by stating that individuals with a conflict of interest have only been involved in the study design and they will not be involved in administering interventions and/or analysing data, or that data and safety monitoring committees will be in place.

# Who has reviewed the study?

The following mandatory text must be included:

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
* Agreeing to be contacted does not oblige them to take part in future research
* They can be removed from this register at any time they wish.
* Add template consent form point 11 to the consent form.

# Further information and contact details:

[For](mailto:Please) further information please contact **[**CI/PI/study team name**]** by **[**telephone, e-mail, in writing**]**

Thank you for reading this information/for considering taking part.

Ensure that all Participant Information Sheets and Consent Form have a version and date.

**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 using MRI within FMRIB, please use the text provided in Appendix A. For other studies using MRI, you may also wish to use this or an adapted version for your PIS.

**What will happen to me if I take part?**

Ensure any pre-screening visits/procedures are detailed in the body of the PIS and state if there are multiple visits required.

A researcher will contact you/ meet you to talk you through the information sheet, explain what you would need to do, and go through a screening form to check if it is safe for you to participate. If you are eligible and agree, we would ask you to come to the **[**name of the imaging centre**]** 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.

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.

You could use/adapt the following text to describe the scan and additional procedures:

***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****]***.