**Note:** The template below contains examples of the main points the information sheet should include. Instructions are *italicised*; example wording is not. Remember to delete all advisory text.

Appendices A-D at the back of this information sheet provide appropriate wording for the following procedures: MRI, TMS, TCS and Induced pain with or without MRI and/or EEG (insert the appropriate wording and delete the appendices before finalising the information sheet). If you are using MEG and/or EEG with any of the other procedures, then please refer to the relevant [CUREC approved information sheet](https://researchsupport.admin.ox.ac.uk/governance/ethics/resources/ap) for appropriate wording to add to this information sheet.

# [Study Title *- this may need to be a shorter, lay version*]

# PARTICIPANT INFORMATION SHEET

Version X, DATE

Central University Research Ethics Committee Approval Reference: [Insert]

We would like to invite you to take part in a research project. This sheet provides some information to help you decide whether to do so. Please take time to read this carefully and discuss it with friends, family or your GP if you wish. If there is anything that you do not understand, or if you would like more information, please ask us. Please take time to consider whether you wish to take part.

What is the purpose of the research?

*Please state the background, purpose and aims of your research, using appropriate wording from the examples in the appendices - Appendix A (MRI), Appendix B (TMS), Appendix C (TCS) and Appendix D (Induced pain with or without MRI and/or EEG. Remember to be brief and don’t use overly complicated language that a* [*layperson*](https://researchsupport.admin.ox.ac.uk/files/writingforparticipantspdf) *wouldn’t understand. Consider what a potential participant would want to know.*

Why have I been invited to take part?

*Explain how they have been identified as a potential participant and mention any inclusion or exclusion criteria, including age range. You should explain how the participant was chosen and say how many other participants will be recruited.*

Example text:

You have been invited to take part in this research because you are healthy, aged *[insert age range]* years old, and speak fluent English. We will be recruiting up to [*insert number*] participants in this research.

[*Add any further inclusion / exclusion criteria*]

Do I have to take part?

*It is important that participants understand that they have a choice about whether they take part. For example, you could say:*

No. It is up to you to decide if you want to take part in this research. You can stop at any time, without giving a reason, [*If appropriate:* and without negative consequences], by contacting us. [*If applicable, state the deadline by which they can withdraw any information e.g. deadline before publication/ submission of thesis*].

*Include* ***one*** *of the following:*

If you withdraw from the study, any information (data) collected up to that point will still be used in analysis

If you withdraw from the study, we will delete/destroy all information (data) collected from you securely

* If you withdraw from the study, we will retain any information (data) collected from you up to that point, unless you tell us otherwise

If you are a student, there would be no academic penalty if you do not want to take part, or if you decide to stop at any point.

What will happen to me if I take part in the research?

*This section should explain what would be involved in your research from a participant’s point of view, and in the order they will experience it. This should include:*

* *where the research will take place, including any information as to what to expect on arrival if a physical visit is planned;*
* *how consent will be taken;*
* *how long the participant will be involved in the research;*
* *what the activity/ activities will involve – e.g., participants completing questionnaires should normally be told what topics would be covered, particularly if any of these are likely to be sensitive. If any unusual equipment is going to be used, it may be helpful to include a picture.*
* *Add appropriate wording from the appendices of this template that apply to your research. Appendix A (MRI), Appendix B (TMS), Appendix C (TCS) and Appendix D (Induced pain with or without MRI and/or EEG.*
* *whether audio or video recordings will be made or photographs taken and the reasons why this is necessary e.g. so I can have an accurate recording of our conversation;*
* *how long the research will last (if this is different);*
* *how often they will need to participate and for how long each time;*
* *details of any pre-screening visits or procedures;*
* *that participants can ask to pause or stop the research activities at any time;*
* *For longer sessions explain that they will be offered regular breaks. If there are multiple activities/ sessions, describe them in turn, using a new paragraph/ section for each.*
* *if any follow-up sessions will be necessary, stating duration and frequencies – if it’s complicated, it may be easier to include a timeline or a diagram to explain;*
* *Add appropriate wording from the templates of any additional approved procedures you will be following.*

Are there any disadvantages or risks in taking part?

*Any reasonably foreseeable discomforts, disadvantages and risks need to be stated. Explain how these risks will be addressed. It is important that participants understand how identifiable they will be from the data and from the research outputs.*

*For appropriate procedure-specific wording refer to Appendix A (MRI), Appendix B (TMS), Appendix C (TCS) or Appendix D (Induced pain with or without MRI and/or EEG) and include all applicable text.*

Are there any benefits in taking part?

*Any benefits to the participants that can reasonably be expected should be stated. However, where there is no intended benefit to the participant from taking part in the project this should be explained. It is important not to exaggerate the possible benefits to the particular participant during the course of the project; this could be seen as coercive. Note that reimbursement should be mentioned in the following section rather than here.*

While there are no immediate benefits for those people participating in the project, it is hoped that what we learn will lead to *[explain anticipated outcomes].*

*Alternatively:*

There will be no direct or personal benefit to you from taking part in this research.

Expenses and payments

You will receive *[x amount/voucher/gift]* for *[participation/reasonable travel costs/meals/child-care].*

*Alternatively:*

There will be no payment for taking part in this research.

What information will be collected and why is the collection of this information relevant for achieving the research objectives?

*Clearly list all types of data (whether identifiable or not) that will be collected from participants (as described on your ethics application form), including*

* *where it will be stored and with what security*;
* *whether data is stored with a unique code rather than their name, and where the linkage document is kept*
* *how long for;*
* *who will have access to it (e.g. The researcher or research team, supervisor, collaborator/ translator/ transcriber/ other authorised personnel)*

*Specify any* [*special category data*](https://researchsupport.admin.ox.ac.uk/governance/ethics/faqs-glossary/glossary#S) *that is to be collected.*

We will keep *[insert details of identifiable information, e.g. contact details, linkage documents]* about you for [*insert time- usually as soon as no longer needed for the research*] after the study has finished. This excludes research documents with personal information, such as paper consent and screening forms, which will be stored safely in lockable cabinets in a secure University of Oxford building for 5 years (screening forms), and for [*insert number*] years after publication or public release of the work of the research (consent forms). Screening forms are accessible by authorised centre staff. *[If you are also storing these items digitally, please add this information here.]*

*Mention if personal details need to be shared (and with whom) in order for participants to receive payments/ vouchers, if applicable.*

The researcher [*and/ or research team, supervisor, collaborator/ translator/ transcriber/ other authorised personnel*…] will have access to the research data.

[*If applicable*: With your consent, we will keep your contact details on a secure database in order to let you know about future studies. We will keep a copy of your consent form with this database, as your consent is our legal basis for re-contacting you under UK data protection law. If you are contacted about a future study, you **do not** have to agree to participate. You can have your details removed from the database at any time by contacting the researchers. If you do not consent for your contact details to be kept, they will be deleted as soon as no longer needed for this study.]

*If applicable*: Research data may be transferred to, and stored at, a destination outside the UK and the European Economic Area. [*If applicable* – Details that directly identify you will be removed and any data transfer will be done securely and with a similar level of data protection as required under UK law. However, you should be aware that countries outside of the UK and European Economic Area may not offer the same level of protection of privacy as that demanded by the law in the UK.]

*If applicable*: I / We may use data from this research in future studies and share this with other researchers (e.g. in online databases). This will only be in a form that does not identify you.  *[Refer to* [*ICO guidance on anonymisation*](https://ico.org.uk/media/1061/anonymisation-code.pdf) *to achieve necessary standard. See in particular appendix 2 and annex 1.]*

Will the research be published? Could I be identified from any publications or other research outputs?

The findings from the research *will/may* be written up [*please describe - e.g. in a thesis, dissertation, academic publications, conference presentations, a report commissioned by an external organisation, websites, videos etc.*]. *Explain whether it will be possible for participants to be identifiable from the outputs and clarify whether they have a choice about this.*

*If applicable*: *I/ We* would like your permission to use direct quotations [*and for your name to be attributed to these/ but without identifying you*] in any research outputs.

*NB: For doctoral students, or other qualifications where a thesis or dissertation needs to be deposited in the* [*Oxford University Research Archive*](https://ora.ox.ac.uk/deposit)*, include the following*: A copy of my thesis / dissertation will be deposited both in print and online in the [Oxford University Research Archive](https://www.bodleian.ox.ac.uk/finding-resources/theses/theses) where [it will be publicly available to facilitate its use in future research/ its access will be restricted].

Data Protection

The University of Oxford is the data controller with respect to your personal data and, as such, will determine how your personal data is used in the research.

The University will process your personal data for the purpose of the research outlined above. Research is a task that we perform in the public interest.

Further information about your rights with respect to your personal data is available from <https://compliance.web.ox.ac.uk/individual-rights>.

Who has reviewed this research?

This study has ethics approval from a subcommittee of the University of Oxford Central University Research Ethics Committee. (Ethics reference: **xxxxx)**.

*Include details of any other reviews, e.g. from a local ethics committee if the research is taking place overseas.*

Who is organising and funding the research?

*Give details of the Organising Department/Researcher and the organisation/company funding the research*

Who do I contact if I have a concern about the research or I wish to complain?

If you have a concern about any aspect of this research, please contact *[insert primary researcher name and University tel. no. / ox.ac.uk email address]* or *[insert supervisor name and University tel. no. / ox.ac.uk email address]*, and we will do our best to answer your query. We will acknowledge your concern within 10 working days and give you an indication of how it will be dealt with. If you remain unhappy or wish to make a formal complaint, please contact the University of Oxford Research Governance, Ethics & Assurance (RGEA) team at [rgea.complaints@admin.ox.ac.uk](mailto:rgea.complaints@admin.ox.ac.uk) or on 01865 616480.

Further Information and Contact Details

If you would like to discuss the research with someone, or if you have any questions, please contact:

[*Insert the name of the primary researcher*]   
[*Insert the name of the Department*]   
[*Insert the postal address*]   
University tel: [*insert number*]   
University email: [*insert address*]

**Insert the appropriate wording from the relevant appendix into the above information sheet and delete all appendices below before finalising the PIS.**

# APPENDIX A

Example: MRI

What is the purpose of the research?

We are interested in understanding how the brain is organised, processes information and performs skills such as thinking and speaking [*expand and amend as appropriate*]. We can investigate this by using a safe technique called Magnetic Resonance Imaging (MRI) to scan the brain. [*Each study should detail specific aspects of brain structure or function being studied and what question the research hopes to answer]*.

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 and explain what will happen in the study. The researcher will go through a screening form with you to check if it is safe for you to take part. Information about the questions we ask as part of screening can be found at <https://www.win.ox.ac.uk/research/take-part/mri-safety-screening-form>.

If you are suitable, and agree, we would ask you to come to the *[FMRIB Building (WIN Centre), OCMR, OxAVIC, OHBA, the West Wing at the John Radcliffe Hospital or Experimental Psychology at Parks Road]* for [*insert number*] visits. Information on what to expect when you come for a scan can be found at <https://www.win.ox.ac.uk/research/take-part/what-to-expect>.

On arrival, one of our research team would describe what participation will involve and answer any questions you may have. If you are happy to continue, they will 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 then the research team can show them to an area where they can wait. Please let us know beforehand if you wear contact lenses or glasses.

Example text:

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*].

*[In cases where Magnetoencephalography (MEG) or EEG are to be applied, refer to the MEG or EEG specific PIS on CUREC website for text to insert here].*

*[In cases where non-invasive brain stimulation techniques TMS or TCS are also to be applied, refer to appendix B and C for text to insert here].*

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 research.

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. Long-sleeved tops (instead of short sleeved, which are normally provided) and MRI-safe headscarves are available on request. You may keep your underwear and socks on, but you will need to remove underwired 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. Please bring your own makeup to reapply. Lockers are provided to secure your personal belongings and clothing.

The way you wear your hair when you go into the scanner is important for your comfort and safety. We would usually ask you to wear your hair down so it can be laid flat under your head. Please let the researcher know if you have plaits, braids, cornrows, dreadlocks, additional permanent hair weaves or hair extensions in advance of your scan.

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

You will be introduced carefully to the scanner 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 recommended to have a hospital (NHS) diagnostic scan arranged. 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.

What information will be collected and why is the collection of this information relevant for achieving the research objectives?

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.

***Frequently asked questions***

Information on what to expect, and a list of frequently asked questions about MRI scanning can be found at <https://www.win.ox.ac.uk/research/take-part/what-to-expect>.

Can I request women-only or men-only scanning staff for my scan?

The radiographers and scanner operators are the ones who will ask you medical questions (in private) on a safety screening form, immediately before your scan. They are also the ones who will be in the scanner room with you as you get into and out of the scanner and will attach any necessary monitoring equipment (such as a device to measure your pulse or breathing rate). 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 researcheris also present at the scan.

Can I have an MRI scan during my period?

It is perfectly safe for you to have an MRI scan with us while you are on your period and there is no requirement to discuss this with your radiographer.

Sanitary pads, tampons, silicone period cups and discs are all fine to wear during your scan. If you are planning to wear absorbent period underwear, please check the label and ensure these don’t contain any metallic antimicrobial fibres.

If you are wearing any pain-management devices such as magnets, tens machines, or sticky patches that provide heat or pain-relieving medications, please remove these prior to your scan.

Is a breastfeeding area available during my visit to WIN as a study participant?

Yes, a quiet private space for breastfeeding can be booked for you. Please request this in advance by contacting the researcher whose study you are participating in.

Is a prayer space available during my visit to WIN as a study participant?

Yes, a quiet private space for prayer can be booked for you. Please request this in advance by contacting the researcher whose study you are participating in.

# APPENDIX B

Example: TMS

What is the purpose of the research?

We are interested in understanding how the brain is organised, processes information and performs skills such as thinking and speaking *[expand and amend as appropriate]*. We can investigate this by using a safe brain stimulation technique, called Transcranial Magnetic Stimulation (TMS). *[Detail specific aspects of brain structure or function being studied and why].*

What will the research involve?

A researcher will go over the information sheet with you and explain what will happen in the study. The researcher will go through a screening form with you to make sure that it is safe for you to take part. If you are suitable, and happy to continue, they will ask you to sign a consent form. This research includes [*insert number]* visits to [*insert location*] in Oxford. Each visit takes no more than [x] hours.

During TMS, a coil is positioned on your head and pulses are used to stimulate the brain. You will hear a ‘click’ sound and may feel a tap on your scalp. You may also feel a brief twitch in your muscles. It should NOT be painful.

*Optional:* We can measure the effects of this stimulation by recording the activity of muscles using a technique called EMG (electromyography). EMG activity of the muscle is measured at the surface of the skin by attaching a sensor (small silver disc). Several sensors will be taped on the skin over muscles on your [*hands/arms/lips – include as appropriate*]. During TMS, muscle movement will be measured using EMG and you will be asked to complete an activity (for example on a computer). At times you may need to move in a particular way, at other times you can relax. The researchers will explain what you need to do before each measurement starts.

[*Insert relevant thresholding or stimulator output info here*] e.g., The intensity of stimulation is varied until the EMG recording consistently shows activity in the muscle in response to the stimulation. Once we have determined the right level of stimulation for you, we proceed with the research.

We will use TMS to stimulate your brain as follows: [*tailored to be research-specific; examples given below*]

1) Single- dual- or triple-pulse stimulation (known as ‘multi-pulse TMS’)

Single pulses, pairs, or triplets of pulses (separated by less than a second) will be applied over the scalp.

2) Low-frequency repetitive stimulation (rTMS at or <1Hz)

The TMS will be applied over the scalp at a maximum rate of one pulse per second (0.6 - 1 Hz). This will last for up to 20 minutes.

3) High-frequency repetitive stimulation (rTMS >1Hz)

Short bursts of up to 5 pulses lasting less than a second will be applied and repeated for a fixed number of pulses. This will last up to [X} minutes.

4) Patterned repetitive stimulation: e.g. theta-burst stimulation will involve bursts of fast pulses applied every 200ms for up to 40 sec total stimulation time.

Example research-specific text:

We will ask you to do some simple tasks before TMS, after TMS or during TMS. These will involve *listening to sounds (presented via earphones)/ watching videos*, and providing responses through either speaking, making movements or pressing buttons. You will also be given computer-based decision-making or problem-solving tasks. Each task lasts no more than *20* minutes and the researcher will clearly explain to you what to do. If necessary, you will be given a chance to practice the task to make sure you understand what to do. The tasks are not designed to be difficult.

What do I have to do?

Please try to get a good night’s sleep the night before the study session, so that you are alert. Please do not drink more than 3 units of alcohol the day before the visit. Please do not drink any alcohol on the day. Please do not use recreational drugs before the visit. You may drink coffee or tea as normal but please do not drink coffee within one hour of the visit. If you are unsure about any of the above, please talk to the researcher before taking part.

Are there any risks in taking part in this research?

TMS carries a small risk of causing seizures (fits) in susceptible individuals, such as people with a family history of epilepsy, with certain neurological (brain) disease or taking certain medications. The risk of a seizure occurring in healthy individuals due to TMS is extremely small. As a precaution, we will go through a screening form with you to make sure that it is safe for you to participate. If you are taking any medication, you should discuss this with the researcher beforehand. If you suffer with migraine headaches, you should not take part in this research.

We recommend that you do not take part in another study using brain stimulation for at least one week after completing this study. This is because the effects of brain stimulation may start to build up if you have multiple sessions close together.

To minimise the possibility of such a build up, we recommend you receive brain stimulation on a maximum of two consecutive days and not more than four sessions in one month.

It is our policy not to give TMS to someone who is pregnant. If there is a possibility that you are pregnant, you must not take part in this research.

What are the side effects of TMS?

Participants may experience some discomfort during TMS. In susceptible individuals, TMS may cause headache, which usually goes away on its own or responds well to over-the-counter painkillers (e.g. paracetamol).

# APPENDIX C

Example: TCS

What is the purpose of the research?

We are interested in understanding how the brain is organised, processes information and performs skills such as thinking and speaking *[expand and amend as appropriate]*. We can investigate this by using a safe brain stimulation technique, called transcranial current stimulation (TCS). [*Detail specific aspects of brain structure or function being studied and why]*.

What will the research involve?

A researcher will go over the information sheet with you and explain what will happen in the study. The researcher will go through a screening form with you to make sure that it is safe for you to take part. If you are suitable, and happy to continue, they will then ask you to sign a consent form. This research includes up to [ ] visits to [ ] in Oxford. Each visit takes no more than [ ] hours.

During your visit we will use a very weak electrical current to stimulate your brain. We will place two large rubber sensors *[insert electrode size here, for example:* 5 cm across by 7 cm long] on your scalp, either with some conducting gel or by placing them into sponges soaked in salty water (saline). The sensors will be held in place with bands wrapped around your head [*refer to inserted picture if desired*].

[*Research specific information on type of stimulation, current, and duration*] *For example:* A very weak current (up to 2 milliamps) is passed through these electrodes for 20 minutes. For most people TCS is painless. Some people do feel a slight tingling or itching feeling under the sensors, especially when the current is switched on. Effects will be minimised by initially increasing the current very slowly. You can ask the researcher to stop the stimulation at any point if you become uncomfortable. Sometimes, participants report experiencing small flashes of light. These may be unusual, but are safe and not unpleasant.

[*Research-specific task information here - For example:* We will ask you to do some tasks before, during or after TCS. This will involve *listening to sounds (presented via earphones)/watching videos*, and providing responses through either speaking, making movements or pressing buttons. You will also be given computer-based decision-making or problem-solving tasks.] Each task lasts XX minutes and the researcher will explain clearly to you what to do. If necessary, you will be given a chance to practice the task to make sure you understand what to do.

Please try to get a good night’s sleep the night before the study, so that you are alert. Please do not drink more than 3 units of alcohol the day before the visit. Please do not drink any alcohol on the day. Please do not use recreational drugs before the visit. You may drink coffee or tea as normal but please do not drink coffee within one hour of the visit. If you are unsure about any of the above, please talk to the researcher before taking part.

Are there any risks in taking part in this research?

TCS uses a very low current and is not known to be harmful. There have been many studies throughout the world using this technique and no side effects have been seen, apart from the slight tingling feeling mentioned above, and occasional headaches. However, as with all techniques that directly stimulate the brain, TCS has the possibility to trigger seizures (fits) in people who are more prone to them. There are no known reports of TCS triggering seizures in healthy participants). We will ask you to fill in a screening questionnaire to make sure it is safe for you to participate. As a precaution, it may not be possible to give TCS to someone with a personal or close family (first-degree relative e.g. parent, sibling, child) [delete as appropriate] history of epilepsy, certain neurological (brain) or psychiatric disorders, or extreme mood fluctuations. If you are unsure, please ask the researchers. If you are taking any medication, you should discuss this with the researcher beforehand.

We recommend that you do not take part in another study using brain stimulation for at least one week after completing this study. This is because the effects of brain stimulation may start to build up if you have multiple TCS sessions close together.

To minimise the possibility of such a build-up, we recommend that participants receive brain stimulation on a maximum of two consecutive days and no more than four sessions in one month.

It is our policy not to give TCS to someone who is pregnant. If there is a possibility that you are pregnant, you must not take part in this research.

# APPENDIX D

Example: Induced pain with or without MRI and/or EEG

What is the purpose of the research?

The goal of pain research is to acquire new knowledge on the changes that occur during short and long-term pain, as well as changes with pain treatment. This requires research on humans and involves experimentally induced painful stimulation. Pain studies will be conducted with or without Magnetic *Resonance Imaging (MRI), Magnetoencephalography (MEG), and/or Electroencephalography (EEG) [delete as appropriate].* These techniques are safe and are used to help us examine changes in brain structure or activity and/or to measure the chemicals in the brain.

What will the research involve?

The research will involve having either one stimulus sustained over tens of minutes, (tonic stimulation) or repeated short stimuli, each lasting a few seconds, in order to induce one or more of the painful perceptions: *[for example: mechanical pain, chemical pain, thermal (hot/cold) pain, electrical pain - please refer to Approved Procedure 19 for sensory stimulation techniques]*. We experimentally induce these painful sensations in a safe, controlled and temporary manner.

*[Explanation of the pain stimulus used in this research must be appropriately given here - please refer to Approved Procedure 19].*

*[In cases where non-invasive brain imaging techniques (MRI, MEG, and/or EEG) are to be applied in the research, for MRI refer to Appendix A for text to insert in here, and for MEG and EEG, refer to MEG or EEG specific PIS on CUREC web page for Approved procedures for text to insert in here].*

Pain is an experience that is strongly influenced by various factors, including thoughts and emotions. In order to understand the complex nature of pain perception, you will be asked to perform additional computer-based or paper and pencil tests. You may also be asked to complete questionnaires asking, for example, about your lifestyle, experiences, or mood [*use appropriate sentence(s) or replace with suitable text for the research]*.

If you agree to take part in this research, we would ask you to come to the [Wellcome Centre for Integrative Neuroimaging (WIN – formerly FMRIB) or OCMR, West Wing, OxAVIC, OHBA for [*insert number*] visits. There is an area in our facilities where an accompanying person can wait. On arrival, one of our research team would meet you to describe what the study involves and answer any questions you may have. If you are happy to participate, we would ask you to sign a consent form, and give you a copy to keep.

Are there any risks in taking part in this research?

Depending on the stimulation used to elicit a painful sensation the following risks might be possible:

*[To be completed appropriately for your research]*.