**Note** text highlighted in yellow will need to be completed appropriately for your study.

Appendices A-D in 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 on the CUREC website for appropriate wording.

Optional statements are highlighted turquoise – delete if not applicable to your research (then delete all advisory text – highlighted yellow)

# [Study Title]

# PARTICIPANT INFORMATION SHEET

Ethics 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 the appropriate wording from the appendices. Appendix A (MRI), Appendix B (TMS), Appendix C (TCS) and Appendix D (Induced pain with or without MRI and/or EEG)]

Why have I been invited?

You have been invited to take part in this research because you are healthy, between [insert lower age limit] and [insert upper age limit] years of age, and speak fluent English. We will be recruiting up to [*insert number*] participants in this study.

[Add any further inclusion / exclusion criteria]

Do I have to take part?

No. It is up to you to decide if you want to take part in this study. We will describe the study, go through this information sheet with you, and answer any questions you may have. If you agree to take part, we will ask you to sign a consent form and will give you a copy for you to keep. However, you would still be free to withdraw from the study at any time, without needing to give a reason. This would not affect legal rights you would receive. If you are a student at the University of Oxford or Oxford Brookes, there would be absolutely no academic penalty if you decide you do not want to take part in this study, or if you decide to withdraw at any point.

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

[Give details as to what will be involved in your research from a participant’s point of view, and in the order they will experience it. If there are multiple study visits, describe them in turn. Give location and duration of all visits.]

Add appropriate wording from the appendices that apply to your study. [Appendix A (MRI), Appendix B (TMS), Appendix C (TCS) and Appendix D (Induced pain with or without MRI and/or EEG)].

[Give details of any follow-up visits, with duration and frequencies].

[You must inform the participant if your research will involve video/audio-taping or photography. Specific consent will be needed if published material identifies the subject].

Are there any risks in taking part in this study?

[For appropriate wording refer to Appendix A (MRI), Appendix B (TMS), Appendix C (TCS) and Appendix D (Induced pain with or without MRI and/or EEG) and include all that apply].

Are there any benefits from taking part in this study?

No. There will be no direct benefit to you from taking part in this study. It is hoped that the results from this research will help us to identify better measures for future studies in patients with medical conditions: for example, pain, epilepsy, memory or movement disorders and surgical conditions. [*Add or delete as necessary*]

[Optional- Will my time/travel costs be reimbursed?]

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

**Or:** There will be no payment for taking part in this study.

What will happen to the data provided?

The information you provide as part of the study is the **research data**. Any research data from which you can be identified (e.g. your name, contact details, date of birth, audio recording, consent form, photographic images), is known as **personal data**. [If applicable to the study: this includes more sensitive categories of personal data (**sensitive data**) such as your racial or ethnic origin or data concerning your health]. It does not include data where the identity has been removed (anonymous data).

We will minimise our use of personal [if applicable: and sensitive] data in the study as much as possible.

The **research data** will be stored confidentially …

[Example: Any MRI imaging and electronic data will be anonymised with a code. All such data are kept on firewall and password-protected computers and any paper information (such as consent forms, and any research questionnaires) would be stored safely in lockable cabinets in a swipe-card secured building and would only be accessed by the research team. Responsible members of the University of Oxford may be given access to data for monitoring and/or audit of the study to ensure we are complying with guidelines.]

Your responses will be [anonymised/ not anonymised]...

**Personal / sensitive data** will be stored confidentially using….

The [researcher and/or e.g. research team, supervisor, collaborator / translator / transcriber…] will have access to personal/sensitive data / research data.

[Note: please encrypt electronic storage devices, especially if you deal with sensitive personal data. Please see [*http://researchdata.ox.ac.uk/home/managing-your-data-at-oxford/storage-and-backup/*](http://researchdata.ox.ac.uk/home/managing-your-data-at-oxford/storage-and-backup/). Please also encrypt data and files before transferring or uploading these, see [*https://www.youtube.com/channel/UC4FTuOgYsOYOGAbpfBZ\_7iw*](https://www.youtube.com/channel/UC4FTuOgYsOYOGAbpfBZ_7iw)]

[*If applicable*] We would like your permission to use direct quotes.

All research data and records will be stored for at least [x] years after publication or public release of the work of the research. *[Note that University policy stipulates a minimum of 3 years after publication, but certain funders may specify longer retention periods and additional data management requirements – see* [*http://researchdata.ox.ac.uk/university-of-oxford-policy-on-the-management-of-research-data-and-records/*](http://researchdata.ox.ac.uk/university-of-oxford-policy-on-the-management-of-research-data-and-records/)*].*  We may retain and store your personal data for an additional period of time as necessary for the purposes of the study, and for further research.

[*If applicable:* Your personal data may be transferred to, and stored at, a destination outside the European Economic Area. We will make sure that identifiable data is removed whenever possible and that any data transfer is done securely and with a similar level of data protection as required under UK law.

*[If applicable*] Sometimes, new methods to analyse data become available after a study has ended. Therefore, we would like your permission to use anonymised data in future studies, and to share data with other researchers (e.g. in online databases). All personal information that could identify you will be removed or changed before information is shared with other researchers or results are made public.

With your consent, we will keep your personal information on a secure database in order to contact your for future studies. *[Delete as necessary]*

Will the research be published?

The research may be published in…

*[Note on student thesis online publication (only relevant if you are a student whose successful thesis will be deposited both in print and online in the University archives) – standard wording in turquoise]:*

The University of Oxford is committed to the dissemination of its research for the benefit of society and the economy and, in support of this commitment, has established an online archive of research materials. This archive includes digital copies of student theses successfully submitted as part of a University of Oxford postgraduate degree programme. Holding the archive online gives easy access for researchers to the full text of freely available theses, thereby increasing the likely impact and use of that research.

The research will be written up as a thesis. On successful submission of the thesis, it will be deposited both in print and online in the University archives, to facilitate its use in future research. The thesis will be openly accessible. [OR, if an application will be made for the thesis to be published with restricted access, please state this here].

Who has reviewed this study?

All research studies are checked by an ethics committee to ensure the research is conducted safely and to the best standards. This research has been reviewed by, and received favourable opinion from, the University of Oxford Central University Research Ethics Committee.

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 study or I wish to complain?

If a participant in University research is ever considered to have suffered harm through their participation, the University has arrangements in place to provide for compensation. If you have a concern about any aspect of this study, please speak to the researcher [name & contact details] or the Principal Investigator [name & contact details] [delete as necessary], who will do their best to answer your query. The researcher should acknowledge your concern within 10 working days and give you an indication of how he/she intends to deal with it. If you remain unhappy or wish to make a formal complaint, please contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 616480, email ctrg@admin.ox.ac.uk, who will inform the chair of the Research Ethics Committee at the University of Oxford.

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 study.

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 <http://www.admin.ox.ac.uk/councilsec/compliance/gdpr/individualrights/>.

Further Information and Contact Details

If you would like to discuss the research with someone beforehand, or if you have any questions afterwards, please contact [Name of Investigator] on [tel. or email].

# Insert the appropriate wording into the information sheet and delete the appendices before finalising the information sheet.

# APPENDIX A

Example: MRI

What is the purpose of the research?

We are interested in understanding how the brain is organized, processes information and performs skills such as thinking and speaking [*expand and amend as appropriate*]. We can investigate this by using Magnetic Resonance Imaging (MRI) brain scans, which are safe and non-invasive. {Each study should detail specific aspects of brain structure or function being studied and what question the study 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 (or meet you) to go over the information sheet, explain the procedures, and go through a screening form with you to check if it is safe for you to participate. If you agree, we would ask you to come to the [Wellcome Centre for Integrative Neuroimaging (WIN – formerly FMRIB), the University of Oxford Clinical Magnetic Resonance Research Centre (OCMR), the Oxford Acute Vascular Imaging Centre (OxAVIC), the Oxford Centre for Human Brain Activity (OHBA) the West Wing at the John Radcliffe Hospital or Experimental Psychology at Parks Road] for [insert number] of visits. On arrival, one of our research team would meet you to describe what participation will involve and answer any questions you may have. The researcher will go through a Screening Form with you to make sure that it is safe for you to participate in the study. If you are happy to continue they will then ask you to sign a consent form. To undergo magnetic resonance scanning you would be asked to lie still on a table inside the MRI scanner. The study would involve having a series of magnetic resonance scans over a period of 45-120 minutes. The entire study might take up one morning or afternoon of your time. The research team can direct an accompanying person to an area where they can wait. Please let us know beforehand if you wear contact lenses or glasses.

[Study-specific task information here]

Example text:

During the scan you will 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 will be asked to perform additional computer-based or paper and pencil tests in a separate room before or after the scan. You will also complete questionnaires asking, for example, about your lifestyle, experiences, or mood.

You will be asked whether you would be willing to have electroencephalographic (EEG) recordings made during the MRI study or in a separate session. This would involve putting a light elastic cap on your head. This cap holds small electrodes able to record the electrical activity associated with performing simple tasks like reading. Recording this activity is safe and painless. It may involve the use of an EEG gel between the electrode and your scalp. EEG recordings during an MRI scan would not lengthen the total time for the scan by more than a few minutes. If you wish, you would be able to wash any EEG gel out of your hair before leaving the Centre.]

[In cases where non-invasive brain imaging techniques Magnetoencephalography (MEG) or EEG are to be applied in the study, refer to MEG or EEG specific PIS on CUREC website for text to insert in here].

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

Are there any risks in taking part in this study?

MRI is safe and non-invasive and does not involve any ionizing radiation (x-rays). However, because it uses a large magnet to work, MRI scans are not suitable for everybody. Because of this, you will be asked pre-screening safety questions to help determine if you are able to take part. Normally, MRI scanning for research purposes would not be performed without further investigation if you have a heart pacemaker, mechanical heart valve, mechanical implant such as an aneurysm clip, hip replacement, or if you carry other pieces of metal that have accidentally entered your body.

While there is no evidence to suggest 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.

If you think you might be claustrophobic, please discuss this in advance with the researcher, or let the radiographer or operator know before your scan.

As some of the scans are noisy, we would 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 pocket less and metal free "pyjama-style" top and trousers, which are available in a range of sizes. You may keep your underwear and socks on but we would ask ladies to remove underwired bras, if you have a suitable non-wired bra you may wear this instead.  Please avoid any fabrics that contain metallic threads or have been silver impregnated (often marketed as anti-microbial/bacterial or anti-odour/stink). Metal jewellery including body piercing must also be removed. Eye shadow and mascara must also be avoided, since some types contain materials that can interact with the magnetic field. If you wish to wear eye makeup to your scan we can provide makeup removal wipes but you are advised to 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.]

Participants will be introduced carefully to the scanner and allowed to leave at any stage. Whilst in the scanner participants have easy access to a call button should they wish to stop the scan or speak with the radiographer or operator.

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.

# APPENDIX B

Example: TMS

What is the purpose of the research?

We are interested in understanding how the brain is organized, processes information and performs skills such as thinking and speaking *[expand and amend as appropriate]*. We can investigate this by using Transcranial Magnetic Stimulation (TMS). {Each study should detail specific aspects of brain structure or function being studied and why}.

What will the study involve?

A researcher will contact you (or meet you) to go over the information sheet and explain the procedures. The researcher will go through a screening form with you to make sure that it is safe for you to participate in the study. If you are happy to continue they will then ask you to sign a consent form. This study includes [insert number] visits to [insert location] in Oxford. Each visit takes no more than [ ] hours.

We will use TMS to stimulate your brain. TMS is a technique that allows us to stimulate the brain by rapid switching of a magnetic field in a coil placed over the head.

Optional: [We can measure the effects of this stimulation by recording the activity of muscles (electromyography; EMG). EMG activity of the muscle is measured at the surface of the skin by attaching an electrode (small silver disc). Several electrodes will be taped on the skin over muscles on your hands and lips.]

During TMS, a coil is positioned over the scalp and single pulses are used to stimulate the brain. [The intensity of stimulation is varied until the EMG recording consistently shows activity in the muscle in response to the stimulation.] [*Insert relevant thresholding or stimulator output info here*] [Once we have determined the minimum intensity at which this activity is observed, we proceed with the research.]

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

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

Single pulses or pairs or triplets of pulses (separated by less than a second) will be applied over the scalp. At the same time, the activity will be measured in your muscles using EMG and/or you will be asked to complete a task on the computer. You will be told to either contract or relax your muscles.

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) for up to 20 minutes.

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

Short trains of up to 5 pulses lasting less than a second will be applied and repeated for a fixed number of pulses.

4) Patterned rTMS: e.g. theta-burst stimulation will involve bursts of high-frequency (50 Hz) triplets applied every 200ms for up to 40 sec total stimulation time; max 600 pulses.

Example study-specific text:

You will be asked to perform simple tasks before TMS, after TMS or during TMS. These will involve listening to sounds (presented via earphones), watching videos, and providing responses either through 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 explain to you what to do before each measurement starts. 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?

Before you take part in our study, we ask that you get a good night’s sleep the night before, so that you are alert. Also, we ask you to refrain from excessive alcohol consumption (more than 3 units) the day before the study and not to drink any alcohol on the day. We also ask that you refrain from use of recreational drugs before the study. You may drink coffee or tea as normal but we ask that you do not have a coffee for one hour before the study. If you are unsure about any of the above, please discuss these with the researcher before taking part.

Are there any risks in taking part in this study?

TMS carries a risk of causing seizures (fits) in susceptible individuals. Seizures were reported in approximately 20 individuals worldwide between 1994 and 2009. This was across more than 6000 research studies and over 60,000 participants. In most cases the seizure was associated with a family history of epilepsy, existing neurological disease (e.g. multiple sclerosis) or medication (anti-depressant or dopamine medication). The risk of a provoked seizure occurring in healthy individuals due to TMS is extremely small. As a precaution, it may not be possible to give TMS to someone with a personal or close family (first-degree relative e.g. parent, sibling, child) [*delete as appropriate*] history of epilepsy, another significant neurological or psychiatric disorder, or extreme mood fluctuations. 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 study.

The risks associated with how often an individual can participate in a non-invasive brain stimulation study are unclear. Many studies use non-invasive brain stimulation to treat disorders (e.g. depression) and administer stimulation daily, as the therapeutic effects are thought to accumulate across sessions. Sessions separated by 48h do not show cumulative effects, however. To minimise the possibility of cumulative effects of brain stimulation for healthy participants not enrolled in treatment studies, we recommend that you should participate in sessions on no more than two consecutive days and no more than four sessions in a month. While no guideline has been provided for a “cooling-off” period between stimulation sessions, some have suggested it to be between 48 hours and one week after stimulation. Therefore, to protect participants from repeatedly being called upon to participate in non-invasive brain stimulation studies (this includes TMS and transcranial current stimulation or TCS), we recommend that the period of abstinence between different brain stimulations would be at least one week.

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

What are the side effects of TMS?

Participants may experience some discomfort during TMS. In susceptible individuals, TMS may cause headache, which usually 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 organized, processes information and performs skills such as thinking and speaking *[expand and amend as appropriate]*. We can investigate this by using transcranial current stimulation (TCS). {Each study should detail specific aspects of brain structure or function being studied and why}.

What will the study involve?

A researcher will contact you (or meet you) to go over the information sheet and explain the procedures. The researcher will go through a screening form with you to make sure that it is safe for you to participate in the study. If you are happy to continue they will then ask you to sign a consent form. This study includes up to [ ] visits to [ ] in Oxford. Each visit takes no more than [ ] hours.

During your visit we will stimulate your brain using a very weak electrical current. This kind of brain stimulation is known as TCS. Two large rubber electrodes [insert electrode size here, for example: 5 x 7 cm2] are placed on the scalp either with some conducting gel or by inserting them into sponges soaked in saline. These are then held in place with bands wrapped around the head [*refer to inserted picture if desired*]. [*Study specific information on type of stimulation, current, and duration*] [For example: A very low direct current (up to 2 milliamps) is then passed through these electrodes for 20 minutes.] For most people TCS is a completely painless procedure, but some people do feel a slight tingling sensation under the electrodes, especially when the current is switched on. Participants usually describe this as being similar to an itching sensation. The effects will be minimised by increasing the current very slowly initially, which usually stops this tingling, but remember you can always ask the researcher to stop the stimulation at any point if you become uncomfortable. On occasion, participants report experiencing small flashes of light but these are not unpleasant. In our experience, participants do not experience any other sensations.

[*Study-specific task information here* - For example: You will also be asked to perform tasks before, during or after TCS. This will involve listening to sounds (presented via earphones), watching videos, and providing responses either through 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 to you what to do before each measurement starts. If necessary, you will be given a chance to practice the task to make sure you understand what to do.

Before you take part in our study, we ask that you get a good night’s sleep the night before, so that you are alert. Also, we ask you to refrain from excessive alcohol consumption (more than 3 units) the day before the study and not to drink any alcohol on the day. We also ask that you refrain from use of recreational drugs before the study. You may drink coffee or tea as normal but we ask that you do not have a coffee for one hour before the study. If you are unsure about any of the above, please discuss these with the researcher before taking part.

Are there any risks in taking part in this study?

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 induce seizures in people who are more susceptible to them (although there are no known reports of this in healthy participants). 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, another significant neurological or psychiatric disorder, or extreme mood fluctuations. If you are taking any medication, you should discuss this with the researcher beforehand.

The risks associated with how often an individual can participate in a non-invasive brain stimulation study are unclear. Many studies use non-invasive brain stimulation to treat disorders (e.g. depression) and administer stimulation daily, as the therapeutic effects are thought to accumulate across sessions. Sessions separated by 48h do not show cumulative effects, however. To minimise the possibility of cumulative effects of brain stimulation for healthy participants in non-treatment studies, we recommend that you should participate in sessions on no more than two consecutive days and no more than four sessions in a month. While no guideline has been provided for a “cooling-off” period between stimulation sessions, some have suggested it to be between 48 hours to one week after stimulation. Therefore, to protect participants from repeatedly being called upon to participate in brain stimulation studies (this includes TCS and transcranial magnetic stimulation or TMS), we recommend that the period of abstinence between different brain stimulations would be at least one week.

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

# 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 pathophysiology and treatment of acute and chronic pain. This requires research on humans and involves experimentally induced painful stimulation. Pain studies will be conducted with or without non-invasive techniques to visualize Central Nervous System (CNS) structure, chemistry, and function, such as Magnetic Resonance Imaging (MRI), Magnetoencephalography (MEG), and/or Electroencephalography (EEG).

What will the study involve?

The study will involve having tonic or repeated physical stimulation 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 study 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 study, 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 website 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 study].

If you agree to take part in this study, 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 is to be done and answer any questions you may have. We would also ask you to sign a consent form, of which you would be given a copy for you to keep.

Are there any risks in taking part in this study?

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

[To be completed appropriately for each study].