There is no set formula for writing a good information sheet, as this depends on the audience and nature of the research. The following points should be considered when writing your information sheet:

- Use clear, non-technical language. We recommend that you refer to the Plain English Campaign: http://www.plainenglish.co.uk/
- Use appropriate language for the target audience. For example, consider the different ways to communicate with primary school children as opposed to their teachers or people with expertise in the area of study as opposed to people with no such expertise.
- Divide the text into paragraphs for ease of reading.
- Consider using sub-headings for clarity.
- Make sure the font and font size are legible.
- Have someone else read through your information sheet before it is circulated.

How long should the information sheet be?
Information sheets should only contain relevant information (i.e., to decide whether to participate in a research project and to inform about legal and regulatory rights).

The length and design of an information sheet should encourage a prospective participant to read it in full. A participant may take more care when reading a concise information sheet and be better informed than if they have read an information sheet that runs into an excessive number of pages.

However, concerning projects that involve 'particularly vulnerable' participants or require access to personal data, the information sheet may need to be longer to cover more detailed information.

In some cases, it is advised to create a cover sheet with the main information as a pictogram or overview page to discuss the details with the participant in detail verbally.

UNIVERSITY OF PLYMOUTH

BRIC BRAIN RESEARCH & IMAGING CENTRE

Information for participants

[*Study Title*] *The title could be the same as in the protocol or a simplified version understandable to a layperson. If the latter, this should be used as the short title in the project proposal. The titles must be consistent throughout the documentation.*

Researcher team:
[*List all names alphabetically including titles and affiliations*]

Principal investigator:
[*Title and full name*]

Ethics Committee Reference Number: [*PEOS #*] *This may not be available at the time the form is submitted for review.*

Thank you for considering participating in this study which will take place [*insert approximate dates*]. 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.

1. What is the research about?

[*Set out the aim of this project/research and the methods to collect information. It would help if you used **language that your intended participants would understand**. Provide a brief outline of the purpose of your study in lay language. Do not cut and paste directly from the research proposal. If applicable, state who the funder of the research is.*]

2. Why have I been invited?

[*Explain specifically why the participant has been invited (e.g. because they have a specific condition or are healthy individuals). State how many participants you intend to involve and their characteristics (e.g., healthy volunteers, people with x condition).*]

3. Do I have to take part?

It is up to you to decide whether to take part. You do not have to take part if you do not want to. If you do decide to take part, [*I/we*] will ask you to sign a consent form which you can sign and return in advance of the [*interview/focus group meeting*] or sign at [*the meeting*].

4. What will my involvement be?

[*Be clear about what participation will involve and how long this might take. E.g. 'You will be asked to participate in an interview/focus group/survey about your experience/knowledge of… It should take approximately…*]

This section details what will be involved in your research study from a participant's point of view and the order they will experience it. If there are multiple study visits, describe them in turn.

- *If research is taking place in a health care or educational setting, make clear which parts are research and which standard care and education.*
- *A table or flow chart can provide clarity when describing a complex series of interventions.*

Consider:

- *How long will the participant be involved in the research, how often will they need to attend a research session, and how long will visits be?*
- *If you randomly allocate participants to study arms, describe what it means in lay terms.*
- *If you are collecting samples, give an idea of the amounts. Saliva volume may be more meaningfully expressed in tablespoons: 5ml is equivalent to 1 teaspoon, and 15ml is one tablespoon.*
- *Outline any plans for long-term monitoring/follow-up.*

Examples:

After the first session, we will carefully consider our methods and safety procedures. There is a chance that further sessions won't be suitable for you due to safety precautions, however this does not mean you cannot have TUS performed at all or in the foreseeing future.

There is a chance that after the first session you no longer will be suitable for this study. This could happen due to the specific tailoring of TUS in this study and its safety precautions. This however does not mean that you are illegible for future TUS studies.

We may reconsider eligibility after your first session. As each TUS study is tailored differently, there may be a chance that this current study is not best fit for you. This does not mean that you cannot have TUS performed at all or in the foreseeing future. If this study proved to not be best fit for you and you would like to participate in other future studies, please let the research know.

5. How do I withdraw from the study?

You can withdraw from the study at any point until ***[****insert date, e.g. when you will begin analysis of the data, or until the publication of the data****]***, without having to give a reason. Withdrawing from the study will not affect you. If you withdraw from the study, we will not retain the information you have provided thus far unless you are happy for me to do so.

Consider

If any questions during the [interview/focus group] make you uncomfortable, you do not have to answer them.

6. What will my information be used for?

The data from the study will be analysed by the research team. Over the coming years, results may be presented at scientific meetings, published in scientific journals, or published on our website. It will not be possible for anyone to identify you from the results, as only aggregated results will be reported.

Sometimes, new methods to analyse data become available after a study has ended. Therefore, we ask for your permission to share your anonymized study data as "open data". This means the anonymized study data will be publicly available to other researchers both inside and outside the European Union. Your anonymised scan data may be used in future studies for purposes not related to this study. It will not be possible to identify you from these data.

With your consent, we will keep your personal information on a secure database in order to contact you for future studies.

7. What are the possible benefits of taking part?

There is no direct benefit to you. We hope that we will gain useful information about [...]. , which may help inform future studies.

8. Are there any possible disadvantages or risks of taking part?

TUS: TUS is safe and non-invasive although participants may experience some discomfort during the stimulation. In susceptible individuals, TUS may cause headache, which usually responds well to over-the-counter painkillers (e.g. paracetamol). TUS will not cause seizures. As a precaution, it will not be possible to give TUS to someone with personal or close family (e.g.: parent, sibling or child) with history of epilepsy, another significant neurological or psychiatric disorder, or extreme mood fluctuations. If you are taking any medication or suffer from migraines, you should discuss this with the researcher beforehand.

MRI: 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. We will ask you to complete a safety questionnaire to make sure that you do not have any metal in your body. Normally, MRI scanning for research purposes is not 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 refrain from taking part in this study.

As the scanner can be noisy, we will give you earplugs. It is important that these are fitted correctly as they are designed to protect your hearing. Some people may experience a mild dizzy sensation as they are moved into the MRI scanner. This is normal and the sensation will fade as soon as you are in the scanner. You will be introduced carefully to the scanner and will be allowed to leave at any stage. While you are in the MRI scanner, you can tell us to stop the scans using the handheld buzzer to speak with us if you feel discomfort or do not wish to continue with the scan. Some people who do not like small spaces (“claustrophobia”) might dislike having an MRI scan. If you think you might be claustrophobic, please discuss this in advance with us.

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.

9. Will I be reimbursed for taking part?

You will receive [£?]. in compensation for your time.

[*Make clear whether they will be compensated for their time, inconvenience or for having to donate samples. If there will be no reimbursement, then make this also clear.*]

10. Will my taking part and my data be kept confidential? Will it be anonymised?

The records from this study will be kept as confidential as possible. Only [*name who will have access*] and the monitoring or audit team approved by the university will have access to the files and any [*e.g., audio tapes*]. Your data will be anonymised; your name will not be used in any reports or publications resulting from the study. All digital files, transcripts and summaries will be given codes and stored separately from any names or other direct identification of participants. Any hard copies of research information will be kept in locked files at all times at [*say where: full address and location*]. All information will be stored electronically using OneDrive and only accessed using password-protected personal computers in a document file that is also password protected.

Limits to confidentiality: 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 and unable to act for themselves; in this case, we may have to inform the relevant agencies of this, but we would discuss this with you first.

The University of Plymouth sponsors this study based in the United Kingdom. We will use information from you to undertake this study and act as the data controller. This means that we are responsible for looking after your information and using it properly. The University of Plymouth will keep identifiable information about you for ten years after the study concludes. Your rights to access, change or move your information are limited, as we need to manage your data in specific ways for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. We will use the minimum personally identifiable information to safeguard your rights.

For more information regarding data confidentiality, you can access the research participant privacy notice for Plymouth University: https://www.plymouth.ac.uk/your-university/governance/information-governance/privacy-notices.

If you have a general question about how the University uses your personal information, wish to exercise any of your rights, or complain about how you believe your data is being processed, don't hesitate to contact the University's Data Protection Officer: dpo@plymouth.ac.uk.

11. What will happen to the results of this study?

[*Reassure potential participants that they will not be identified from any report or publication placed in the public domain. If they are (for instance, with images of faces), it will be necessary to obtain specific consent for this.*

It would help if you informed potential participants of your intentions concerning:

- *Publishing research findings.*
- *Presenting your results at conferences.*
- *Feeding back findings to participants themselves. Will you provide them with a summary, or*
- *add in a link to a website from which they could get the information, or ask them to contact*
- *you?*

Indicate that this study is part of an educational project, such as fulfilling requirements for a B.Sc. For example, Some of the research being undertaken will also contribute to fulfilling an academic requirement (e.g., an undergraduate dissertation).]

12. Who do we share your data with?

Extracts of your anonymised data may be disclosed in published works posted online for use by the scientific community. Your data may also be stored indefinitely on external data repositories (e.g., the UK Data Archive) and be further processed for archiving purposes in the public interest or for historical, scientific, or statistical purposes. It may also move with the researcher who collected your data to another institution in the future.

13. What if we find something unexpected?

If we detect something we think is worthy of further investigation by a qualified professional, we will contact your GP. No information other than your name will be conveyed unless you specifically request it. You would not be informed unless the doctor considers the finding has clear implications for your current or future health.

14. Who has reviewed this study?

This study has undergone ethical review following the University of Plymouth Research Ethics Policy and Procedure. This study has been reviewed and approved by the [*add the name of the committee*], application number [*PEOS application number*].

15. Participation in future research

As a result of UK GDPR, retention of contact details for communication of future research opportunities now requires evidence of consent for holding such identifiable details (i.e. the consent form must be retained for as long as the details are held). Provide as much detail as possible to participants at data collection and consider how consent may be revisited if data plans for data reuse change and re-consent are required. If your supervisor intends to approach participants in the future, make it clear where their details will be kept - for instance:

If you are interested in participating in future research, a staff member from the University of Plymouth will contact you regarding participation in ethically approved research. Your contact details will then be held separately from this study on [*describe arrangements – e.g., a password-protected computer in the Department of XY]* and agreeing to be contacted does not oblige you to participate in future research.

16. Data Protection Privacy Notice

The University of Plymouth Research Privacy Policy can be found at: https://www.plymouth.ac.uk/research/governance/research-participant-privacy-notice.

The legal basis used to process special category personal data (e.g., data that reveals the racial or ethnic origin, political opinions, religious or philosophical beliefs, trade union membership, health, sex life or sexual orientation, genetic or biometric data) will be for scientific and historical research or statistical purposes.

To request a copy of the data held about you, please get in touch with dpo@plymouth.ac.uk.

17. What if I have a question or complaint?

If you have any questions regarding this study, please get in touch with the researcher, [*X]*, on [*email address*].

If you have any concerns or complaints about this study's ethical conduct, please contact the Research Administrator, Faculty of Health Ethics and Integrity Committee, University of Plymouth, Level 2 Marine Building, Drake Circus, Plymouth, Devon, PL4 8AA
Email: Research.Ethics@plymouth.ac.uk

- The University of Plymouth Research Ethics Policy can be found here: https://www.plymouth.ac.uk/uploads/production/document/path/12/12337/General_Research_Ethics_Policy__final_draft_V1.0_Oct19.pdf.

- The University of Plymouth Research Data Policy can be found here: https://www.plymouth.ac.uk/uploads/production/document/path/6/6913/Research_Data_Policy.pdf.

- The University of Plymouth Code of Good Research Practice can be found here: https://www.plymouth.ac.uk/uploads/production/document/path/12/12338/Code_of_Good_Research_Practice.pdf.

If you are happy to participate in this study, please sign the consent sheet attached/below.

Thank you for reading this information sheet.
[*THANK YOU***]**

ADDITIONAL:

Will I be recorded and how will the recorded media be used?
You must obtain the participant's permission to record their activities on audio or video media. You must ensure that there is a clear understanding as to how these recorded media will be used. For instance, if you record a seminar, history and symptoms taking, you must not publish or broadcast the recording, show it in public, or deposit it in an archive without the performers' permission. Storage and eventual disposal of interview recordings which contain sensitive material should also be covered here.

Example paragraph:
'The audio and/or video recordings of your activities made during this research will be used only for analysis and for illustration in conference presentations and lectures. No other use will be made of them without your written permission, and no one outside the project will be allowed access to the original recordings.'

If you plan to use the recording in a publication or broadcast or deposit it in an archive, it is usually best to prepare and sign a separate release form for each item used.

What if new information becomes available?
If it is likely that additional information becomes available during the course of the research, you will need to tell the participant about this. You could use the following:

Example paragraph:
'Sometimes, during a research project, new information becomes available about the treatment/ intervention/ device being studied. If this happens, your researcher will tell you about it and discuss whether you want to continue in the study. If you decide to withdraw, arrangements will be made for you to withdraw without any consequences. If you decide to continue in the study, you will be asked to sign an updated consent form.'

Transfers of your data outside Europe
If data is transferred out of the European Union state, whether the country the data is being transferred to is on the EU list of adequate countries (this can be found here https://ico.org.uk/for-organisations/guide-to-data-protection/principle-8-international/#adequate) or the safeguards that apply, i.e., transfer by consent or contractual necessity, transfer subject to standard contractual clauses approved by the ICO, US's privacy shield, etc.

Note, this section applies if you use online services to process data (e.g., online questionnaire services or analytics). If you intend to use online services that transfer personal data to a country outside the European Union for processing and you find that they are not covered by an adequacy decision or you cannot find any binding corporate rules attached to them, ***do not use them*** *as you will be in breach of GDPR. You can use the following form of words for data transfers.*

Example paragraph:
Your data will be transferred to [state name of a third country] for processing. The European Commission has determined that [the third country your data is being transferred to] provides adequate protection for your data: [insert a link to the relevant adequacy decision; see also http://ec.europa.eu/justice/data-protection/international-transfers/adequacy/index_en.htm]

OR

Your data will be transferred for processing to [state name of international organisation and reference the binding corporate rules safeguarding the data, where there are made available, or the means by which to obtain a copy of them].