Preparing Participant Information Sheets

This guide is intended to help you create participant information sheets for your research project.

It is recommended that the content of an information sheet is:

- Relevant to the proposed research;
- Accurate and concise;
- Clear, simple and understandable from a lay person's perspective;
- Presented on the headed paper of the institution carrying out the research; and
- Appropriate for the cultural and social context in which it is being given.

It is recommended that the content of an information sheet does not include:

- Any abbreviations, jargon, or technical terms; or
- Bias or coercion or any inappropriate inducements.

Below are examples of the main points an information sheet should include:

Title of study: Does this explain the study in simple English? One consistent title should appear on all your study documents and be self-explanatory. Any acronyms need to be written out in full.

Name of Researcher: You should insert in here your name, and your course

Invitation paragraph: You need to explain that you are asking the participant to take part in research. For example:

> "*You are being invited to take part in a research project …Before you decide on whether to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully before you decide whether or not you wish to take part. You are welcome to discuss this project with others if you wish before you make your decision. Please ask us (provide email address/other contact details) if there is anything that is not clear or if you would like more information.*"

What is the purpose of the study: Purpose is an important consideration for participants, so you should present it clearly and succinctly, in the context of other work in the field. Remember to be brief and avoid overly complicated language. Primarily the purpose may be educational, such as undertaking a research study as part of a course. If this is the case, then this should be made clear.

Why have I been chosen? You should explain briefly, why and how the participant has been chosen and how many others will be in the study.

Do I have to take part: You should explain that taking part in the research is entirely voluntary and that refusal to agree to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled and the participant may discontinue participation at any time. For example:

> "*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) and you can still withdraw at any time without it affecting any benefits that you are entitled to in any way. You do not have to give a reason.*"

"If you do withdraw you should, however, note that the University will continue to process the information you have already provided. It will only do this for research purposes and in an anonymised way and in a way that you cannot not be identified."

What do I have to do? / What will happen to me if I take part? To answer this question, try to 'put yourself in the subject's shoes.' Set down, briefly and clearly, what you will expect from the participant, such as lifestyle, medical health or dietary restrictions, attending scheduled visits, keeping diaries, filling out questionnaires etc.

You should explain:
• How long the participant will be involved in the research, how long the research will last (if this is different), how often they will need to participate and for how long each time (you should explain if travel expenses are available);
• What exactly will happen (e.g., blood tests, interviews?);
• Where a participant is to be interviewed, it might be helpful to explain the questioning style (e.g., clarify if questions will enable open as well as closed answers to be given in relation to a particular topic; clarify which aspects of the topic participants should be able to discuss in-depth and which more broadly);
• The participant's responsibilities, setting down clearly what you expect of them;
• The research methods you intend to use, in simple and accessible language; and
• Whether there are any lifestyle restrictions as a result of participating.

Use the most appropriate format to demonstrate their involvement (diagrams/tables). The detail will depend on the complexity of the study. It may help if the information is displayed in a flow chart or grid indicating what will happen at each visit, where appropriate.

For Health related research – Make it clear which procedures are over and above those used in standard treatment or management. It is also essential to explain whether any normal treatment will be withheld for all or part of the study. Long-term monitoring/follow up should be mentioned.

If the study involves video/audio-taping or photography, you should explain what is intended and include the confidentiality issues. Specific consent will be needed if material of any sort will be published that identifies the subject, otherwise the information and data we obtain from the participant will be anonymised.

You should set out (in simple format) the research methods you intend to use.

Expenses and payments? You should explain if any expenses (e.g. travel, meals, child-care, compensation for loss of earning etc.) are available. You should consider whether any gifts or vouchers which you intend as a thank-you should be detailed in the information sheet.

What are the possible disadvantages and risks of taking part? Briefly outline any risks, discomfort or inconvenience the participant may experience. You should consider carefully how to explain any risks involved in your study, as this can be difficult.

Risks may include possible side effects from medication, potential injury from exercise trials, or the use of additional ionising radiation within x-rays, or distress from recollecting unpleasant memories and feelings.

For example if you are discussing or exploring sensitive issues with a participant that could upset them then you need to identify this so the participant is fully aware.
You should make appropriate support services available for the participant to access if further support is required.

What are the possible benefits of taking part? Explain these clearly. Where there is no intended benefit for the participant, this should be stated. DO NOT exaggerate the possible benefits. It would be reasonable to say something similar to:

We cannot promise the study will help you but the information we get from the study will help to improve the treatment of people with (name of condition)
Or
We cannot promise the study will help you but the information we get from the study will help to increase the understanding of (name the focus of the research)

It is however important to remind the participant of this: *We are a university and so it is part of our reason for being that we advance knowledge through research as well as through teaching. Your participation in this research helps us to do that.*

What if there is a problem? You should inform participants who to contact if they have a complaint about the research study, their experience, and/or the researcher. A contact number should be given. This may be the researcher, in the first instance, who can try to resolve the problem. However, a participant may not wish to complain to the researcher if he/she is the object of the complaint, and may wish to make a more formal complaint, for example:

If you have a concern about any aspect of this study, you should ask to speak to the researcher by email (XXX@edu.salford.ac.uk) who will do their best to answer your questions.

Following this, if you have any issues or complaints, you may contact the research supervisor xxx by email (XXX@salford.ac.uk) or by telephone (0161 295 XXXX)

Or

the Associate Dean Research xxxxx by email (xxx@salford.ac.uk) or by telephone on (0161 295 xxxx)

You need to provide contact details / location of the University Complaints Procedure.

In addition to identifying a clear complaints procedure, you need to identify appropriate redress and/or compensation that would be available if the research participant came to any harm as a result of the research study. As a student of the University and/or NHS employee you need to fully explore the compensation arrangements. If there are no such compensation/insurance/indemnity schemes in place then this needs to be clearly explained.

Will my taking part in the study be kept confidential? / What will happen to the results of the research project? You should tell the participant how their confidentiality will be safeguarded during and after the study. You may wish to tell the participants how your procedures for handling, processing, storage and destruction of their data match the Cadicott principles and/or General Data Protection Regulation (GDPR).

The participant should be told:

- how their data will be collected.
- that it will be stored safely, giving the custodian and level of identification, for example:
    - individual participant research data, such questionnaires/interviews/samples/ x-rays will be anonymous and given a research code, known only to the researcher
    - A master list identifying participants to the research codes data will be held on a password protected computer accessed only by the researcher

  - hard paper/taped data will be stored in a locked cabinet, within locked office, accessed only by researcher
  - electronic data will be stored on a password protected computer known only by researcher
- What it will be used for. For example, it must be clear that the data may be used for future studies and whether further approval will be sought, although this will only ever be in an anonymised way.
- Who will access to view identifiable data (authorised persons such as researchers within the team, supervisors, sponsors and for monitoring the quality, regulatory authorities /R&D audit).
- Importantly, if it is to be shared with a third party, who the third party is, and the reasons for sharing the data, NOTE: this should generally only be done in an anonymised way.
- How long will it be retained and that is will be disposed of securely.

Here is the link to the University's Research Privacy Notice that sets out details about the University's processing of personal information for research purposes:
https://www.salford.ac.uk/privacy/introduction/research-privacy-notice

Example introductory statement includes:

All information, which is collected, about you during the course of the research will be kept strictly confidential, and any information about you which leaves the university will have your name and address removed so that you cannot be recognised.

What will happen if I want to stop being part of the study? There are different positions to take on what will happen if a participant withdraws from a study and it is up to the researcher to determine what is applicable to their study and ensure that this is clearly communicated to the participant prior to them agreeing to take part. Three possible scenarios include:

If you withdraw from the study, all the information and data collected from you, to date, will be continue to be used, however your name will be removed from all the study files.
Or
If you withdraw from the study we will destroy all your identifiable samples/ tape recorded interviews, but we will need to use the data collected up to your withdrawal.
Or
You can withdraw from the study/treatment but keep in contact with us to let us know your progress. Information collected may still be used. Any stored blood/tissue samples or taped interviews that can still be identified as yours, will be destroyed if you wish.

What will happen to the results of the research study? Participants often want to know the results of the study in which they were involved. You should tell participants what will happen to the results, whether they will be published and how the results will be made available to them. You should add that they will not be identified in any report/publication unless they have given their specific consent.

The University may keep the data and use it in future studies. If we do this, it will only be in a completely anonymised fashion.

Who is organising or sponsoring the research? The answer should include the organisation or company sponsoring the research and funding the research if these are different (e.g. Research Charity, academic institution, NHS employee).

Further information and contact details: The additional information that participants require can sometimes be divided into the following four categories. You need to identify where to locate additional information or who to contact to address the different enquires.

1. General information about research (e.g. list relevant documents or websites)
2. Specific information about this research project (e.g. contact details of researcher)
3. Advice as to whether they should participate (e.g. contact details of a different health care professional who can provide impartial advice)
4. Who they should approach if unhappy with the study (e.g. contact details of complaints procedure if not listed earlier)

A minimum prerequisite in this section is that the contact details of the researcher (email address) should be clearly identified.

Any email addresses given must be University of Salford email addresses rather than personal ones.

Finally… The information sheet should state that the participant will be given a copy of the information sheet and, if appropriate, a signed consent form to keep.

Thank you
Remember to thank the individual for taking time to read the information sheet.

Date The information sheet should be dated.

Additional question to include in an information sheet if the research involves producing recorded media:

Will I be recorded and how will the recorded media be used?
You need to obtain the participants' 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 music or theatre performance, 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 can also be an issue to address. For example:

> *"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 often better to prepare and sign a separate release form for each item used.