Guidance on Completing a Participant Information Sheet

Central to human subject research is the informed consent process. This process must ensure that research participants are provided with all the relevant information they need in order to decide if they would like to participate in a study. It is therefore important that information given to participants, before obtaining their written informed consent to take part, is clear and concise and fully explains all aspects of the research.

It is extremely important that care and attention is given to the documentation supplied to research participants to allow participants the opportunity to give their 'fully' informed consent to take part in the research.

What are the key points an information sheet should contain?

The information sheet should give a brief summary of the research project and its aims, clearly outlining the entire research process in a language accessible for a non-expert audience. It should also outline what participation means in practice; how long participation takes, where it takes place and what it involves.

It may be necessary to draft more than one information sheet if you need to communicate to participant groups with different needs (such as teachers and children) or if your project involves different types of participation (some participants asked to complete anonymous questionnaires only, while others will be interviewed and audio recorded). Each participant should be able to understand from an information sheet exactly what participation would involve for them.

The following list is not exhaustive but gives an idea of the main topics to be covered:

- Explain that participation is always voluntary and that participants can withdraw at any time;
- Outline the nature and aims of the research;
- Explain exactly what participation means in practice (when, where, who, what);
- Outline clearly the inclusion and exclusion criteria for the study;
- Outline any risks, inconvenience or discomfort that could reasonably be expected to result from the study;
- Describe the benefits for participants (if relevant, as there might not be any direct benefits for the participant);
- Explain how privacy and confidentiality would be maintained.

Language and Layout

There is no set formula for writing a good information sheet as this depends on the audience and nature of 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 needed to communicate to 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 (such as a questions and answers);
- 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. in order to decide whether or not to participate in a research project). It is recommended that, where appropriate, an information sheet contains information in the order specified under the headings given overleaf.

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 thereby, be better informed than if (s)he has read an information sheet that runs into several pages. However, with respect to projects that involve 'particularly vulnerable' participants and/or which require access to 'sensitive' personal data the information sheet may need to be relatively longer in order to cover more detailed information.

Model Information Sheet

1. **Research Project Title**
   Is the title self-explanatory to a lay person?

2. **Invitation Paragraph**
   Explains that the potential participant is being asked to take part in a research project.

   Example paragraph:
   'You are being invited to take part in a research project. Before you decided it is important for you to understand why the research us being done and what participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this.'

3. **What is the project's purpose?**
   The background, aims and objectives and duration of the project should be given here

4. **Why have I been chosen?**
   You should detail what the inclusion criteria are. You should explain how the participant was chosen and how many other participants will be recruited to the study.

5. **Do I have to take part?**
   You should explain that taking part in the study 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. The participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.

   Example paragraph:
   'It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep (and be asked to sign a consent form – if applicable). You can withdraw at any time without giving a reason and without it affecting any benefits that you are entitled to.'

6. **What will happen to me if I take part?**
   You should state 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 detail whether travel expenses will be reimbursed.

   You should explain exactly what will happen (e.g. blood tests, MRI scanning, interviews etc.) and set out simply the research methods that you intend to use.

7. **What do I have to do?**
   State if there are any lifestyle restrictions as a result of participating.

8. **What are the possible disadvantages and risks of taking part?**
   Any reasonable foreseeable discomforts, disadvantages and risks need to be stated. Researchers should make known to the participants any predictable detriment arising from the proposed research process. Any unexpected discomforts, disadvantages and risks to participants, which arises during the research, should be brought immediately to their attention.

9. What are the possible benefits of 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 stated clearly. 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.

Example opening sentence:
'Whilst there are no immediate benefits for those people participating in the project, it is hoped that this work will….'

10. What if something goes wrong?

You should inform participants how complaints will be handled and what redress may be available (i.e. what the process is). You need to distinguish between handling complaints from participants regarding their treatment by researchers and something serious occurring during or following their participation in the project (e.g. a reportable serious adverse event).

In the first instance you should inform the participants which member of the research project they should contact should they wish to raise a complaint (this is most likely to be the Principal Researcher or Supervisor). However the participants should also be informed that should they feel their compliant has not been handled to their satisfaction (e.g. by the PR or the supervisor) that they can contact the Chair of the UCL Research Ethics Committee.

11. Will my taking part in this project be kept confidential?

You need to obtain the participant's permission to allow restricted access to information collected about them in the course of the project. You should state that all information will be kept strictly confidential and explain what measures will be taken to ensure this.

Example paragraph:
'All the information that we collect about you during the course of the research will be kept strictly confidential. You will not be able to be identified in any ensuing reports or publications.'

You should always bear in mind that you, as the researcher, are responsible for ensuring that when collecting or using data, you are not contravening the legal or regulatory requirements in any part of the UK.

12. What will happen to the results of the research project?

You should be able tell the participants what will happen to the results of the research (i.e. when the results are likely to be published, where they can obtain a copy of the published results, whether they be told which arm of the project they were involved in) and add that they will not be identified in any report or publication.

Depending on the nature of your proposed project, you may need to include a statement indicating that the data collected during the course of the project might be used for additional or subsequent research.

13. Who is organising and funding the research?

You should state the organisation or company that is sponsoring or funding the research.

14. Contact for further information

You should give the participant a contact point for further information. This can be your name, address and telephone number or that of another researcher in the project (if this is a supervised-student project, the address and telephone number of the student's supervisor).

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 and remember to thank the participants taking part in the project.

Questions to include if the research involves producing recorded media

Will I be recorded and how will the recorded media be used?

You need to 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 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 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 archive, it will usually be best to prepare and sign a separate release form for each item used.

Questions to insert into an information sheet if the research project is an overseas clinical trial

What is the drug or procedure that is being tested?

You should include a short description of the drug or device and give the stage of development. You should also state the dosage of the drug and method of administration.

What are the alternatives for diagnosis or treatment?

For therapeutic research the participant should be told what other treatments are available.

What are the side effects of any treatment received when taking part?

For any new drug or procedure you should explain to the participants the possible side effects. If they suffer these or any other symptoms they should report them next time you meet. You should also give them a contact number and name if they become in any way concerned. The name and contact number of a person to contact in the event of an emergency (if that is different) should also be given. The known side effects should be listed in terms the participant will clearly understand (e.g. 'damage to the heart' rather than 'cardiotoxicity'; 'abnormalities of liver tests' rather than 'raised liver enzymes'). For any relatively new drug it should be explained that there may be unknown side effects.

What are the possible disadvantages and risks of taking part?
For projects where there could be harm to an unborn child if the participant were pregnant or became pregnant during the project, the following (or similar) should be said

'*It is possible that if the treatment is given to a pregnant woman it will harm the unborn child. Pregnant women must not therefore take part in this project; neither should women who plan to become pregnant during the project. Women who are at risk of pregnancy may be asked to have a pregnancy test before taking part to exclude the possibility. Women who could become pregnant must use a contraceptive during the course of this project. Any woman who finds that she has become pregnant while taking part in the project should immediately tell her doctor.'*

Use the above statement carefully. In some circumstances (e.g. terminal illness) it would be inappropriate and insensitive to bring up pregnancy.

If future insurance status (e.g. for life insurance or private medical insurance) could be affected by taking part this should be stated (if e.g. high blood pressure is detected). If the patients have private medical insurance you should ask them to check with their company before agreeing to take part in the study. They will need to do this to ensure that their participation will not affect their medical insurance.

You should state what happens if you find a condition of which the patient was unaware. Is it treatable? What are you going to do with this information? What might be uncovered?

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

'Sometimes during the course of a research project, new information becomes available about the treatment/drug that is being studied. If this happens, your doctor 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 your care to continue. If you decide to continue in the study you will be asked to sign an updated consent form.'

Top tips for designing information leaflets for children and young people

It is important for researchers to provide children and young people with enough information to allow them to make a fully informed decision to take part in a study. Well designed information leaflets may also help researchers recruit more children and young people into a study and may possibly retain children in that study.

- **Five W's to make it simple:**

What – What is the study about? What will happen to me in the study?
Why – Why is the study being done?
Where – Where will the study take place?
When – When will the study begin and possibly finish?
Who – Who will lead the study?

- **Information broken up into blocks**

Top-tip: break the information into smaller chunks, so it is clear for children and young people to read. A long piece of writing puts children and young people off reading it!

- **Use different media and formats (e.g. DVDs)**

Top-tip: think about different ways to communicate with children and young people by using different formats, for example produce a DVD that explains the study, or use websites.

- **Presentation – colour, pictures, layout**

Presentation is important because it's the first thing children and young people will notice about a leaflet, the more colourful the better!

Top-tip from a young person: put pictures in because it means something, not because you feel you have to! I still won't understand the information by adding a picture to the text.

- **Information needs to be planned (not just thrown in!)**

Top-tip: information needs to flow, don't repeat sentences, or put words in that don't mean anything.