Guidelines for Writing a Participant Information Sheet

All research involving human participants should be described in a Participant Information Sheet. This sheet is given to participants when they are invited to participate and should be retained by them. Potential recruits to your research study must be given sufficient information to allow them to decide whether or not they want to take part. The Participant Information Sheet should form part of the application to the St. Patrick's University Hospital Research Ethics Committee. The Information Sheet should be separate from the Consent Form.

The scope and depth of the Participant Information Sheet will vary depending upon the scale and type of research activity. However, regardless of the complexity of the research proposal or the degree of involvement of participants, there are a number of common guidelines that should be applied.

General

Headed paper must be used and always include the contact details of the Principal Investigator.

Anything to be read by a participant in a research project should be written in simple, non-technical terms and be easily understood by a layperson. Use short words, sentences and paragraphs. Technical terms and jargon should be avoided. Any necessary simplification should not have the effect of understating any risks or of glossing over inconvenience or discomfort. The provision of a Participant Information Sheet is not a substitute for talking to the participant.

Different study groups may require separate information sheets. For example children and vulnerable adults will require suitably worded information sheets.

The Participant Information Sheet should always contain statements on the following:

a) The purpose of the investigation, the nature of the procedures, the risks (including psychological distress) and the possible benefit to the individual or to society.
b) A statement that the participant may decline to participate without giving reasons or incurring displeasure or penalty.
c) A statement that the participant will be free to withdraw at any time without giving a reason and without incurring displeasure or penalty.
d) A statement about the availability or non-availability of compensation for injury, where the Research Ethics Committee considers that the risks of any intervention warrant it.
e) An invitation to ask for more information.

Part 1: Introduction

1. The information sheet must include the title of the study and state that it is a Participant Information Sheet. Is the title self-explanatory to a layperson? If not, a simplified title should be included.
2. The objective of the study should be clearly stated.

Part 2: Invitation to take part in the study

This should explain that the participant is being asked to take part in a research study. The following is a suitable example:
You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. This Participant Information Sheet will tell you about the purpose, risks and benefits of this research study. If you agree to take part, we will ask you to sign a Consent Form. If there is anything that you are not clear about, we will be happy to explain it to you. Please take as much time as you need to read it. You should only consent to participate in this research study when you feel that you understand what is being asked of you, and you have had enough time to think about your decision. Thank you for reading this.

[Note: The fact that approval has been granted by a Research Ethics Committee or by the Irish Medicines Board should not be referred to in any way that may cause potential volunteers to think that the project is specially recommended or is safe.]

Part 3: Purpose of the Study

The background and aim of the study should be given here. Also mention the duration of the study. Avoid being technical or using unexplained abbreviations. It should ideally have one sentence each covering:

1. the general subject of the research
2. what question the study is designed to answer
3. why this person has been asked to participate (You should explain how the participant was chosen and how many other participants will be studied)
4. how this person has been identified or contacted for the study

Part 4: Taking part – what it involves

The section should clearly state what taking part in the study will involve for the participant. Potential risks should not be understated or misrepresented as less serious than they are. The following questions are some of the things that should be covered in this section:

Do I have to take part?

You should explain that taking part in the research is entirely voluntary. You could use the following 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 you decide to take part, you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect your rights in any way.

What will happen to me if I take part?

You should explain what exactly will happen e.g. interviews, blood tests, x-rays, etc. Whenever possible you should draw a simple flowchart or plan indicating what will happen at each visit (if appropriate). You should set out simply the research methods you intend to use e.g. survey, questionnaire, randomised trial etc… Providing a simple definition of the methodology may help. What are the participant's responsibilities? Set down clearly what you expect of them.

How long will my part in the study last?

You should say 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 visit your office or laboratory (if this is appropriate) and how long these visits will be.

What do I have to do?

Are there any lifestyle restrictions? You should tell the participant if there are any dietary restrictions. Can the participant drive, drink, take part in sport? Can the participant continue to take their regular medication? Should the participant refrain from giving blood? What happens if the participant becomes pregnant?

What is the procedure being tested?

Where appropriate, you should include a short description of the device or procedure and give the stage of development.

What are the possible benefits in taking part?

Point out benefits the participant can get from participating. For example, if the study includes an assessment of cognitive function, the participant will be able to learn more about their own memory.

What are the possible disadvantages and risks of taking part?

If there are no foreseeable risks attached to taking part, say so here. If there are, it is very important that you state what they are and how you plan to a) safeguard the participant and b) deal with anything that might happen. Note that your study protocol must include a description of how you will deal with problems that could arise.

Example: Study includes a questionnaire that measures depression and anxiety

The study includes a questionnaire that measures your well-being in the recent past. You might find, while you are answering it, that you would like to talk to someone about some of the issues it raises. We will be happy to recommend someone to you. [Note: if you are carrying out research, you must avoid getting involved yourself with the participant's problems, but you should be able to refer them for appropriate help. These sources of help or onward referral must be planned in advance of commencing the study.]

For studies where there could be harm to an unborn child if the participant were pregnant or became pregnant during the study, 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 study, neither should women who plan to become pregnant during the study. Women who are at risk of pregnancy may be asked to have a pregnancy test before taking part to exclude the possibility of pregnancy. Women who could become pregnant must use an effective contraceptive during the course of this study. Any woman who finds that she has become pregnant while taking part in the study should immediately tell her research doctor.

[Note: Use the pregnancy statement carefully. In certain circumstances (e.g. terminal illness) it would be inappropriate and insensitive to bring up pregnancy.]

There should also be an appropriate warning and advice for men if a treatment used in the study could damage sperm, which might therefore lead to a risk of a damaged foetus.

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.)

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

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

Where appropriate, you should explain to the participants any possible side effects. You should also give them a contact name and number to phone if they become in any way concerned. The name and number of the person to contact in the event of an emergency (if that is different) should also be given.

What if something goes wrong?

Where there are potential side-effects or adverse events attached to the study, or where a risk has been identified, the information sheet should describe what measures are in place to deal with these, should they arise.

What happens at the end of the study?

You should be able to tell the participants what will happen to the results of the research. When are the results likely to be published? Where can they obtain a copy of the published results? Will they be told which part of the study they were in? You might add that they will not be identified in any report/publication.

If a treatment has been administered, will the participant have access to this treatment after the study finishes?

What happens if I change my mind during the study?

You should make it clear to participants that they are entitled to change their mind about participation at any time during the course of the study without disadvantage or penalty to themselves.

What if I have a complaint during my participation in the study?

You should inform participants how complaints will be handled and what redress may be available. Is there a procedure in place? You will need to distinguish between complaints from participants as to their treatment by members of the research team and something serious happening during or following their participation in the research i.e. a reportable serious adverse event.

Whom do I contact for more information or if I have further concerns?

You should give the participant a contact point for further information. This can be your name or that of another researcher involved in the study.

Part 5: Confidentiality

You will need to obtain the participant's permission to allow restricted access to any information collected about them in the course of the study. The information sheet should describe what happens to the information collected in the study and contain a statement assuring the participant that any information pertaining to them will be treated in the strictest confidence.

Example:

All information that is collected about you during the course of the research will be kept strictly confidential and will not be shared with anyone else. The information collected in this research study will be stored in a way that protects your identity and will be maintained subject to legal obligations on the Hospital or its employees, as required by law or other applicable national guidelines.. [If you are collecting sound or video recordings:] The recordings will be transcribed for analysis. We will store the original recordings securely for [length of time] after which they will be destroyed. Results from the study will be reported as group data and will not identify you in any way.

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 Ireland or in any other participating country, in the case of a multi-centre study. This is not the responsibility of the REC.

Part 6: Summary

This section should reiterate that participants should contact the researcher to clarify any points on which they remain unclear. Therefore, it should contain the name, address and telephone number of the person who should be contacted (the Principal Investigator or a designated individual).

It should emphasise again that the participant is free to refuse to take part in the study without any disadvantage and that should they agree to take part, that they can change their mind at any point during the study and decide not to continue in the study without any disadvantage.

Remember to thank your participant for taking part in this study!

The participant information sheet should be dated and given a version number.

The Participant Information Sheet should state that the participant will be given a copy of the information sheet and a signed consent form to keep.