Guidance on drawing up information sheets for human research projects

Information sheets to obtain informed consent from people to participate in a research study are essential. While their content will vary according to each study, general principles remain. Here are some tips to help you draw up your information sheet. What is a great help is to imagine that you are the potential research participant – what would you like to know? Write in a friendly tone, be open and honest, use simple language, ask for participation and all should be well. The example at the end does not contain all the following elements, but it is important to include the relevant information:

1. Include the study title, as well as logos of the parties involved in the study.
2. As an introduction, greet the reader, say who you are and which institution you represent. Some useful greetings are: 'Hello', 'Dear Parent', 'Dear Clinic Staff', 'Dear Student', 'Dear Colleague' – it is unwise to use 'Dear Volunteer' when the reader has not yet been asked to volunteer.
3. Give a brief background or reason for the study. Explain why you have approached the potential research participant.
4. Explain what you would like to do, how often you need to do it, what specimens might be required, any reimbursement, payments or insurance, risks and benefits, discomforts, possible complications – then ask for participation.
5. Reassurance is necessary. Emphasise that participation in the study is completely voluntary, that one may decline [a softer word than refuse] to participate without penalty, that one may change one's mind and withdraw from the study without any penalty and without having to explain why one withdrew. Explain how confidentiality will be ensured, what will be done if you find an abnormality and take great care to reassure parents that no child will be forced to participate even if a parent has given permission for participation. Remember that if children are able to understand what will be done they must give consent as well. The parent should be the judge of the ability to understand.
6. Offer the possibility of obtaining more information, for example give the name and telephone number of a contact person. In the event that there are any risks in your study, this is not optional – it must be done. Give the hours during which the person may be contacted.
7. Be polite and friendly; do remember that everybody has freedom to participate – this is the principle of autonomy, a cornerstone of ethics.
8. The risks and benefits of the study must be explained.
9. There must be a statement on whether the participant will be reimbursed for their time, expenses and inconvenience. The amount must be stated, and explained in the protocol (how the amount was determined). Remember that reimbursement is not a benefit nor is it compensation.
10. There must be separate consent, i.e. a separate signature, for recording of interviews, focus group discussions, etc.
11. There must be a statement that the research will adhere to the Declaration of Helsinki (2013).
12. For any biological specimens such as blood or tissue, it must be stated when and for what it will be used, and whether it will be stored, where and for how long. The participant also has to give specific consent for any future use of that stored specimen, and there must be information on what tests may be done in future.
13. There must be a separate informed consent form for genetic testing. A participant may agree to the main study but not to the genetic testing; having a separate form will facilitate that. A separate form also provides opportunity for providing more information. Information must be in lay terms that are easy to understand.

Here is an example. It's not perfect, nothing ever is but it should help

Hello

We are scientists from the South African Medical Research Council and are investigating the quality of the diet that Western Cape children eat and whether this has any effect on school results.

Why are we doing this?

Research in developing countries in South America and Asia have shown that if energy and certain

mineral intakes are low, children get more minor illnesses, they miss school and so their school results are not as good as they might be. We don't know if this is true in the Western Cape so will be grateful if you and your children will participate in a study to examine this.

What do we expect from the participants in the study?

We think that if the amount of iron in the diet is increased slightly, minor illnesses such as colds and influenza may be less common. Your child's school has been selected because earlier studies there have shown that iron intake of the children is often lower than it should be. With the help of a biscuit company we have developed a biscuit that is fortified with a little iron but looks and tastes as it would normally. We wish to compare the effects of the two identical tasting biscuits, one of which will contain some iron and the other will not. To do this we will shuffle names of all participating children and place the names into two groups. One group would get the biscuit fortified with iron and the other group will get the normal biscuit. Each school day for a full school year teachers will give out the biscuits which will be in packets with the particular child's name on. Only the people who packed the biscuits will know what is in each packet. What type of biscuit is being eaten by each particular child is recorded separately and this information will be kept confidential until the very end of the study when the code will be broken. Records will be kept of attendance at school and of any illnesses. In addition, we need to measure the iron levels in the blood of each participating child, before the study begins, and at the end. Nursing sisters will take one 5ml [1 teaspoon] sample at each of the occasions provided that the child agrees. Sterile [free of germs], disposable equipment will be used once only, so there is no chance of any transfer of infection from one child to another. The technique is safe and there is only a slight prick as the needle is placed through the skin. To lessen the discomfort of this prick, a local anaesthetic ointment will be used on the skin. Over the years we have sampled blood from many thousands of children in this way without any problems.

May I withdraw my child from the study?

Certainly, you may do this at any time without having to give a reason. Remember that the study is completely voluntary and not taking part in it, or withdrawing from it, carries no adverse consequence of any sort – schooling will not be influenced.

If you have any queries, more information may be obtained from Doctor A. N. Other at telephone number (021) 123-4567. Dr Other is available 24 hours.

If you are happy to allow your child to take part in the study, please read and sign the attached consent form.

Contact details of the SAMRC Ethics Committee

Ms Adri Labuschagne, tel.: (021) 938-0687; e-mail: adri.labuschagne@mrc.ac.za The Committee may be contacted during office hours.