The University of Nottingham
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UNIVERSITY OF NOTTINGHAM MEDICAL SCHOOL ETHICS COMMITTEE

Information sheet for Normal Healthy Volunteers

The guidance which follows applies primarily to multi-centre pharmaceutical studies and encompasses the ICH Good Clinical Practice guidelines. However, the principles and much of the content will be of use to researchers writing information sheets in their particular fields, for trials involving normal healthy volunteers. You will find it helpful to refer also to other guidelines produced for writing patient information sheets (The Association of the British Pharmaceutical Industry: Guidelines for Medical experiments in Non-patient Human Volunteers March 1988).

Potential recruits to your research study must be given sufficient information to allow them to decide whether or not they want to take part. An Information Sheet should contain information under the headings given below where appropriate, and in the order specified. It should be written in simple, non-technical terms and be easily understood by a lay person. Use short words, sentences and paragraphs.

Use headed paper of the institution/research unit where the research is being carried out. Please use the format laid out below. Unheaded paper is not acceptable.

University of Nottingham, School of
Address of Unit

Insert Title of Project here: Is the title self explanatory to a lay person? If not, a simplified title should be included.

Name of Investigators*:*

Healthy Volunteer's Information Sheet

Invitation paragraph

This should explain that the research volunteer is being asked to take part in a research study. The following is a suitable example:

"You have been invited to take part in a research study. Before you decide 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 and discuss it with friends and relatives if you wish to. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether you wish to take part or not. If you decide to take part you may keep this leaflet. Thank you for reading this."

Background

The background and aim of the study should be given here. Also mention the duration of the study.

What does the study involve?

You should say how long the research volunteer will be involved in the research, how long the research will last(if this is different), how often they will need to visit and how long these visits will be and if travel expenses are available. What exactly will happen eg blood tests, x-rays, interviews etc. Whenever possible you should draw a simple flowchart or plan indicating what will happen at each visit. What are the volunteer's responsibilities? Set down clearly what you expect of them.

You should set out simply the research methods you intend to use – the following simple definitions may help:-

<u>Randomised Trial:</u>

Sometimes because we do not know which way of treating research volunteers is best, we need to make comparisons. People will be put into groups and then compared. The groups are selected by a computer which has no information about the individual – i.e. by chance. People in each group then have a different treatment and these are compared.

You should tell the research volunteers what chance they have of getting the study drug/treatment e.g. a one in four chance.

<u>Blind Trial:</u>

In a blind trial you will not know which treatment group you are in. If the trial is a double blind trial, neither you nor your doctor will know in which treatment group you are (although, if your doctor needs to find out he/she can do so).

Cross-over trial:

In a cross-over trial the groups each have the different treatments in turn. There may be a break between treatments so that the first drugs are cleared from your body before you start the new treatment.

Placebo:

A placebo is a dummy treatment such as a pill which looks like the real thing but is not. It contains no active ingredient.

Why have you been chosen?

You should explain how the research volunteer was chosen and how many other research volunteers will be studied.

Do you 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."

What do I have to do?

Are there any lifestyle restrictions? You should tell the research volunteer if there are any dietary restrictions. Can the research volunteer drive? Drink? Take part in sport? Should the research volunteer refrain from giving blood? What happens if the research volunteer becomes pregnant.

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 side effects of any treatment or procedures received when taking part?

For any new drug or procedure you should explain to the research volunteers the possible side effects eg how much discomfort they may experience if any or possible bruising etc. If they suffer these or any other symptoms they should report them next time you meet. 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.

The known side effects should be listed in terms the volunteer 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?

You should state clearly what are the possible adverse effects of taking part.

For studies where there could be harm to an unborn child if the research volunteer 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 women 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'.

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

You should also state the exclusion criteria for the study where relevant.

If future insurance status e.g. for life insurance or private medical insurance, could be affected by taking part this should be stated (if eg high blood pressure is detected or hepatitis C).

You should state what happens if you find a condition of which the research volunteer was unaware. It should be made clear that the results will be disclosed to the subject (please refer to notes 5 and 6 of the guidelines with regard to HIV and Hepatitis). Is it treatable? What are you going to do with this information? What might be uncovered? And state what your proposed duty of care procedure is.

What if something goes wrong?/Who can I complain to.

You should inform volunteers how complaints will be handled and what redress may be available. Is there a procedure in place? Usually this will involve initially approaching the lead investigator and if no satisfactory outcome is achieved then they should be directed to the Chairman of the Ethics Committee. Contact details for the lead investigator and the Ethics Committee Office should be included as follows:

"In case you have a complaint on your treatment by a member of staff or anything to do with the study, you can initially approach the lead investigator. If this achieves no satisfactory outcome, you should then contact the Ethics Committee Secretary, Mrs Louise Sabir, Division of Therapeutics and Molecular Medicine, D Floor, South Block, Queen's Medical Centre, Nottingham, NG7 2UH. Telephone 0115 8231063. E-mail louise.sabir@nottingham.ac.uk."

You will need to distinguish between complaints from research volunteers as to their treatment by members of staff which may be dealt with locally and something serious happening during or following their participation in the trial i.e. a reportable serious adverse event which must be reported to the Ethics Committee. Failure to do so would amount to serious academic misconduct.

Where there are no Association of British Pharmaceutical Industry (ABPI) or other no-fault compensation arrangements, and the study carries risk of physical or significant psychological harm, the following should be said:

"In the unlikely event that you suffer injury to yourself or damage to your property as a result in taking part in this research, the University does have an insurance policy to cover harm arising as a result of the defect in the design of the study. In addition, all medical practitioners taking part in the research have personal medical negligence cover."

If the study is a drug company sponsored project where there are ABPI or other no-fault compensation arrangements the following (or similar) should be included for information:

"Compensation for any injury caused by taking part in this study will be in accordance with the guidelines of the Association of the British Pharmaceutical Industry (ABPI). Broadly speaking the ABPI guidelines recommend that 'the sponsor' without legal commitment, should compensate you without you having to prove that it is their fault. This applies in cases where it is likely that such injury results from giving any new drug or any other procedure carried out in accordance with the protocol for the study. 'The sponsor' will not compensate you where such injury results from any procedure carried out which is not in accordance with the protocol for the study. Your right at law to claim compensation for injury where you can prove negligence is not affected."

Will my taking part in this study be kept confidential?

In accordance with the current Data protection Act you will need to obtain the research volunteer's permission to allow restricted access to the information collected about them in the course of the study. You should explain that all information collected about them is necessary for carrying out the study and will be stored on a database which is password protected and strictly confidential. If the data is to be released to a third party you should say so and indicate that it will be anonymised and cannot be traced to them. A suggested form of words:

All information which is collected about you during the course of the research will be kept on a password protected database and is strictly confidential. Any information about you which leaves the research unit will have your name and address removed so that you cannot be recognised from it.

In the case of study where blood samples are being taken for communicable diseases such as HIV and Hepatitis B or C it should be made clear to the volunteer that in order to protect laboratory staff, the blood sample will be marked "infectious risk". You should consider therefore how to anonymise the sample to avoid a breach of confidentiality. In addition the subject should understand that other relevant medical practitioners and the Chairman of the Ethics Committee will be informed in the event of a positive test.

You should always bear in mind that you, as the researcher, are the "data controller" as defined by the Data Protection Act and therefore responsible for ensuring that when collecting or using data, you are not contravening the legal or regulatory requirements in any part of the UK. This is not the responsibility of the Ethics Committee.

You should explain that the research volunteer's own GP will be notified of their participation in the study where relevant.

What will happen to the results of the research study?

You should be able to tell the research volunteers 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 arm of the study they were in? You might add that they will not be identified in any report/publication.

Who is organising and funding the research?

The answer should include the organisation or company sponsoring or funding the research (e.g. Medical Research Council, Pharmaceutical Company, Charity, academic institution). Also include if there is any material benefit from doing the study e.g. "The project will receive funding for each subject entered into the study and the money will be used to pay research staff salaries".

Who has reviewed the study?

You may also wish to say that this study has been reviewed and approved by the University of Nottingham Medical School Ethics Committee.

Contact for Further Information

You should give the research volunteer a contact point for further information. This can be your name or that of another doctor/nurse involved in the study.

Remember to thank your volunteer for taking part in the study.

The Research Volunteer Information Sheet should be dated and given a version number so that when amendments are made it is clear which is the correct version.

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