

These guidelines apply to all research projects where human subjects are involved in the study

GUIDELINES FOR RESEARCHERS PATIENT INFORMATION SHEET & CONSENT FORM

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 patients, patient volunteers and healthy volunteers. You will find it helpful to refer also to other guidelines produced for writing patient information sheets.

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 layperson. Use short words, sentences and paragraphs. 'The readability' of any text can be roughly estimated by the application of standard formulae. Checks on readability are provided in most word processing packages.

Use headed paper of the hospital/institution where the research is being carried out. Patient Information Sheets submitted to an MREC should be headed simply 'Hospital/Institution/GP Practice headed paper'.

If you are a local researcher for an MREC approved study, the Patient Information Sheet should be printed on local hospital/surgery paper with local contact names and telephone numbers before it is submitted to the LREC.

Unheaded paper is not acceptable.

1. Study title

Is the title self explanatory to a layperson? If not, a simplified title should be included.

2. Invitation paragraph

This should explain that the patient 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. Please take time to read the following information carefully and discuss it with friends, relatives and your GP 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.'

Consumers for Ethics in Research (CERES) publish a leaflet entitled 'Medical Research and You'.

This leaflet gives more information about medical research and looks at some questions you may want to ask. A copy may be obtained from CERES, PO Box 1365, London N16 0BW.

Thank you for reading this.'

3. What is the purpose of the study?

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

4. Why have I been chosen?

You should explain how the patient was chosen and how many other patients will be studied.

5. 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. This will not affect the standard of care you receive.'

6. What will happen to me if I take part?

You should say how long the patient will be involved in the research, how long the research will last (if this is different), how often they will need to visit a clinic (if this is appropriate) and how long these visits will be. You should explain if the patient will need to visit the GP (or clinic) more often than for his/her usual treatment and if travel expenses are available. What exactly will happen e.g. 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 patient'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: -

Randomised Trial:

Sometimes because we do not know which way of treating patients 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.

Patients in each group then have a different treatment and these are compared. You should tell the patients what chance they have of getting the study drug/treatment e.g. a one in four chance.

Blind trial:

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.

7. What do I have to do?

Are there any lifestyle restrictions? You should tell the patient if there are any dietary restrictions.

Can the patient drive, take part in sport? Can the patient continue to take their regular medication?

Should the patient refrain from giving blood? What happens if the patient becomes pregnant? Explain (if appropriate) that the patient should take the medication regularly.

8. 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. Patients entered into drug trials should be given a card (similar to a credit card) with details of the trial they are in. They should be asked to carry it at all times.

9. What are the alternatives for diagnosis or treatment?

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

10. What are the side effects of taking part?

For any new drug or procedure you should explain to the patients 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 name and number to phone if they become in any way concerned.

The known side effects should be listed in terms the patient will clearly understand (e.g. 'damage to the heart' rather than 'cardio toxicity'; '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.

11. What are the possible disadvantages and risks of taking part?

For studies where there could be harm to an unborn child if the patient 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.'

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 the treatment 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.) If the patients have private medical insurance you should ask them to check with the company before agreeing to take part in the trial. 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? e.g. high blood pressure, HIV status.

12. What are the possible benefits of taking part?

Where there is no intended clinical benefit to the patient from taking part in the trial this should be stated clearly.

It is important not to exaggerate the possible benefits to the particular patient during the course of the study, e.g. by saying they will be given extra attention. This could be seen as coercive. It would be reasonable to say something similar to:

'We hope that both (all) the treatments will help you. However, this cannot be guaranteed. The information we get from this study may help us to treat future patients with (name of condition) better.'

13. What if new information becomes available?

If additional information becomes available during the course of the research you will need to tell the patient 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 research doctor will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw your research doctor will make arrangements for your care to continue. If you decide to continue in the study you will be asked to sign an updated consent form.

Also, on receiving new information your research doctor might consider it to be in your best interests to withdraw you from the study. He/she will explain the reasons and arrange for your care to continue.'

14. What happens when the research study stops?

If the treatment will not be available after the research finishes this should be explained to the patient. You should also explain to them what treatment will be available instead. Occasionally the company sponsoring the research may stop it. If this is the case the reasons should be explained to the patient.

15. What if something goes wrong?

You should inform patients 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 patients as to their treatment by members of staff (doctors, nurses etc.) and something serious happening during or following their participation in the trial i.e. a reportable serious adverse event.

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

'If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you wish to complain about any aspect of the way you have been approached or treated during the course of this study, the normal

National Health Service complaints mechanisms may be available to you.'

Where there are ABPI or other no-fault compensation arrangements the following (or similar) should be included:

'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 at 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. Copies of these guidelines are available on request.'

16. Will my taking part in this study be kept confidential?

You will need to obtain the patient's permission to allow restricted access to their medical records and to the information collected about them in the course of the study. You should explain that all information collected about them will be kept strictly confidential. A suggested form of words for drug company sponsored research is:

'If you consent to take part in the research any of your medical records may be inspected by the company sponsoring (and/or the company organising) the research for purposes of

analysing the results. They may also be looked at by people from the company and from regulatory authorities to check that the study is being carried out correctly. Your name, however, will not be disclosed outside the hospital/GP surgery.’ or for other research:- ‘All information which is collected about you during the course of the research will be kept strictly confidential. Any information about you which leaves the hospital/surgery will have your name and address removed so that you cannot be recognised from it.’

You should explain that for studies not being conducted by a GP, the patient’s own GP will be notified of their participation in the trial. This should include other medical practitioners not involved in the research who may be treating the patient. You should seek the patient’s agreement to this.

In some instances agreement from the patient that their GP can be informed is a precondition of entering the trial.

17. What will happen to the results of the research study?

You should be able to tell the patients 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.

18. 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).

The patient should be told whether the doctor conducting the research is being paid for including and looking after the patient in the study. **This means payment other than that to cover necessary expenses** such as laboratory tests arranged locally by the researcher, or the costs of a research nurse. You could say:-

‘The sponsors of this study will pay (name of hospital department or research fund) for including you in this study’ or

‘Your doctor will be paid for including you in this study.’

19. Who has reviewed the study?

You may wish to give the name of the Research Ethics Committee(s) which reviewed the study (you do not however have to list the members of the Committee).

20. Contacts for Further Information

You should give the patient 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 patient for taking part in this study!

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

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

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(Form to be on headed paper)

Centre Number: :
Study Number:
Patient Identification Number for this trial:

CONSENT FORM

Title of Project:

Name of Researcher:

Please initial box

1. I confirm that I have read and understand the information sheet dated
(version) for the above study and have had the opportunity to ask questions.
2. I understand that my participation is voluntary and that I am free to withdraw at any time,
without giving any reason, without my medical care or legal rights being affected.
3. I understand that sections of any of my medical notes may be looked at by responsible
individuals from [company name] or from regulatory authorities where it is relevant to my
taking part in research. I give permission for these individuals to have access to my records
4. I agree to take part in the above study.

Name of Patient	Date	Signature
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Name of Person taking consent (if different from researcher)	Date	Signature
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Researcher	Date	Signature
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1 copy for patient; 1 copy for researcher; 1 copy to be kept with hospital notes