

ETHICS COMMITTEES

Checklist for writing a patient information sheet

(These are the questions your patient information sheet should seek to answer.)

- Has the information sheet a clear and unambiguous heading?
- Is the word 'Research' in the title of the consent form, and is it in bold?
- Is the language throughout the sheet easy to understand?
- What is the purpose of the study?
- Why has this patient been chosen?
- Does the patient have to take part?
- What happens if the patient takes part?
- Research methods - randomised trial, blind trial, cross-over trial, placebo
- What does the patient have to do?
- What drug or procedure is being tested?
- What are the alternatives for diagnosis or treatment?
- What are the side effects of taking part?
- What are the possible disadvantages and risks of taking part?
- What are the possible benefits of taking part?
- What if new information becomes available (during the study)?
- What happens after the research study?
- What if something goes wrong?
- Will patient confidentiality be maintained?
- What will happen to the results of the study?
- Who is organising and funding the research?
- Who has reviewed the study?
- Who can the patient contact for further information?

The consent form should be a separate document from the patient information sheet.

SAMPLE CONSENT FORM FOR RESEARCH STUDY

Centre Number:

Research study Number:

Patient Identification Number for this research study:

Title of Project:

Name of Researcher:

**Please tick
to confirm**

I have read the information sheet for the above research study.

I have had the opportunity to ask questions about the research study, and to discuss it with family and friends.

I understand the purpose of the research study, and how I will be involved.

[I understand, and accept, that if I take part in the research study I will/may not gain any direct, personal benefit from it.]

[I understand, and accept, that as is explained in the information sheet the treatment which I will receive/procedures which will be carried out may possibly have some side effects.]

[I understand that all information collected in the research study will be held in confidence and that, if it is presented or published, all my personal details will be removed.]

[I give permission for responsible individuals from regulatory authorities, or from [____] to have access to my medical notes where it is relevant to my taking part in the research. This is on the understanding that no personal details which might identify me will be presented or published without my permission.]

I confirm that I will be taking part in this research study of my own free will, and I understand that I may withdraw from it, at any time and for any reason, without my medical care or my legal rights being affected.

I agree to take part in the above research study.

Signed _____ Date _____

Person taking consent _____ Date _____

Researcher (if different from above) _____ Date _____

*1 Copy for Patient, 1 Copy for Researcher, 1 Copy for Hospital Notes