What is 'informed consent'?

A doctor, nurse or other researcher should always ask your permission to enter you into a clinical trial. They cannot enter you into the trial if you do not give your consent.

There are a few exceptional circumstances where the consent process is different, and people might be entered into a trial without their consent. For example, in a trial of the treatment of head injuries or dementia an individual may not be able to give their consent. In these cases consent may be obtained from a relative or other legal representative and there will be additional safeguards to protect the participants.

Where clinical trials involve children the consent process is also different and will be fully explained by the person recruiting to the trial.

To help you decide whether you want to take part in a trial, the researcher should explain:

- the aim of the study - what it is trying to find out
- how you will be treated and what you will need to do
- what the possible risks and benefits are.

It is important that you are satisfied that you have enough information to make a decision and to give your **informed consent**. You should feel free to ask any questions that are

important to you in helping you to reach a decision. You should also feel satisfied that you have been given enough time to think about the trial and what it will mean to you.

The person inviting you to take part in the trial should first discuss the study with you and answer your immediate questions. They should also give you an information leaflet about the trial that you can take away and read in your own time. You may want to discuss it with your family or friends and consider any practical issues, such as extra appointments and tests.

If you decide that you do want to take part you will be asked to sign a form that says that you agree to join the trial and that you have decided to do so of your own free will. You will be given a copy of the signed consent form to keep. If English is not your first language, the trial should be explained to you in your preferred language. You should also be given a consent form that has been written in your preferred language.

The process of informed consent should continue throughout the trial. The researchers should continue to give you information and answer your questions. They should let you know if any new relevant information comes up during the trial so that you can re-think your decision, and withdraw if you want to.

If you decide not to take part in the trial your decision will be respected and you do not have to give a reason. You will continue to receive the appropriate medical treatment that any other person would receive. Remember that even after you have given your consent you can leave the trial at any time without giving a reason.

What happens during a trial?

As well as carrying out tests to find out how well a treatment is working, researchers will also look out for any side effects and you may be asked questions about any new symptoms you have.

Researchers will also look at the wider effects of a treatment on your life as a whole, not just its effects on symptoms. There are also detailed tests and questionnaires that are used to measure people's 'quality of life' so you may be asked:

- if you are able to take part in your usual day-to-day activities
- if you need any extra help around the home or to look after your family
- if you feel happy or sad, anxious or depressed.

Some clinical trials will also look at the cost-effectiveness of treatments and their effects on other aspects of care, so you may also be asked about how the treatment affects other areas of your life such as:

- whether you are able to work during the treatment
- the number of times you visit your doctor and nurse
- travel.

What happens at the end of a trial?

Some trials can run for many years so it may be some time before the results of a trial are known. At the end of a trial the results will be made available to everyone who took part if they want them. They will also be published so that others can use the information to help them make decisions about treatment and health care. The researchers have a duty to publish the results, regardless of what they show, and also show how the results add to available knowledge.

If you are having a new treatment as part of a trial you may not always be able to continue on this treatment when the trial ends. It may be some time before a new treatment is provided by the NHS. In this case you will be given the standard treatment. In some circumstances you may be able to buy the new treatment.

Will my information be confidential?

If you agree to take part in a clinical trial, all your trial records and any information that is collected about you will be kept confidential, in the same way as your medical records. The researchers cannot tell anyone that you are in the trial without asking you first. If your doctor or consultant is not the person who recruited you onto the trial, it can be helpful for them to be told you are in a trial as they will be responsible for your day-to-day health care; but they can only be told with your permission.

Once the trial has finished the results are usually published and often presented at conferences. No name or any information that can identify you will be used in any reports about the trial.

What happens if something goes wrong?

Before any trial can start, arrangements have to be put in place in case something goes wrong and people are harmed. Research ethics committees can refuse approval for trials where there is no insurance or other provision for compensation.

Pharmaceutical companies are insured so that if a patient is damaged by their drug, compensation can be paid. However, it is rare for patients to be seriously harmed by trial treatments, although some may cause unpleasant side effects.

Trials funded by other organisations may not have this kind of insurance, but a payment may be made if something does go wrong. Individual NHS trusts are responsible for insuring themselves against damage caused by their own studies.

Before giving your consent to take part in a clinical trial you may want to find out exactly what arrangements have been made for compensation.

How can I find out about trials that are happening now?

It can be difficult to find a suitable trial to take part in. There are a number of registers of different trials or organisations that can help you, and some of these are listed at the end of this booklet. If you would like to take part in a clinical trial but have not been asked, you should discuss it with your doctor or nurse as they will normally need to refer you. They may also know of a trial that would be suitable for you.

It is important to remember that there may not be a trial which is suitable for you.

What should I ask before I join a trial?

These are some of the questions you may like to ask before deciding whether to take part in a clinical trial.

Some general questions:

- What is the aim of the trial and how will it help people?

- Who is funding the trial?

- What treatment will I get if I don't take part in the trial?