

■ What can I do if I have any questions or problems?

Researchers must tell you about any risks or potential problems. They are trying to find out what medicine or treatments work or work best and if there are possible problems for patients arising from them.

- *What are the possible problems I might have?*
- *Can I get compensation if taking part in the research harms me?*
- *Who can I talk to if I have any questions, concerns or problems? Is their phone number on the information sheet?*

■ Who will researchers tell that I am taking part?

The researchers will have arrangements to make sure information about you is kept confidential but you may want to ask what these are.

- *How will my results be kept confidential?*
- *Will my GP be told about the research?*
- *Who will see my records?*
- *Will information about me be identified?*
- *Will information about me be given to other researchers?*

■ Can I know the research results?

If you take part in research, you can see the results of tests or information about you under the Data Protection Act. However, if you are in a blind trial neither you nor the researcher will know your personal results

until the trial is finished. Most research is published in the medical press. If you are interested in the overall results of the study, ask the researchers to give you publication details. Some studies last several years and so the results may not be published for some time.

■ Can research be done on children?

Only if the parents agree. Children should be asked their views and, if they are able to make their own decisions, allowed to decide for themselves. Research, which can be done equally well on adults, should not be done on children. Research, which does not benefit the child, must not involve more than a very small risk. Children who want to should be able to have a parent stay with them during research tests or treatment.

- *Are there any risks for your child in taking part in the study?*
- *What are their views about it?*
- *Is there a leaflet for children that explains the research?*
- *Will I have help with transport, or somewhere to stay in hospital with my child, if I need this?*

This leaflet is also available in Bengali, Cantonese, Somali, Turkish and Vietnamese and on tape in English, Somali and Sylheti.

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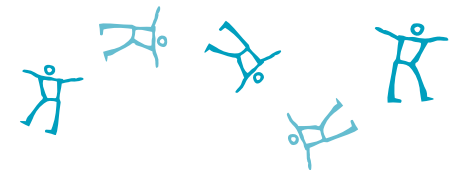
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medical research and you ▶▶▶



What you need to **think about**

The researchers, who may be doctors, nurses, midwives or other staff, must explain the research to you in detail and give you written information about the study to take home with you. If you agree to take part in the research, the researchers will ask you to sign a consent form. Here are some questions you may want to ask before you sign it.

- How was I chosen?
- What will happen to me? Will I have tablets, or injections? Will equipment be fitted onto me? How often will this happen, or for how long? Will it hurt?
- What are the possible side effects of the research?
- How long will the research take?
- Will I have to make extra visits to the hospital, or stay in longer? Will my fares or expenses to and from appointments be paid?
- What kind of care will I have if I do not take part in the research?
- Will the researchers collect information about my genes?
- If you are pregnant, how might the research affect your baby?

■ What is the research for?

Research is often done with patients as part of their treatment. You may want to know if there are any problems with the treatment you are currently receiving.

The research might not help you, but you may decide it is worth taking part because it might help people in future. Some research is paid

for by charities or by the government, and some by commercial companies that are looking for things they can patent. If a company gets a patent, it is the only company allowed to make and sell the new medicine or treatment for a period of time.

- Who is sponsoring the research?

■ Do I have to decide at once?

No. You can ask for time to think about it. You may want to talk to family or friends or your GP. Whatever they say, the decision is yours. You can ask for an interpreter or advocate to be with you when you talk to the researchers.

■ What if I say no or change my mind?

You can refuse to take part in research. You can change your mind or withdraw at any time, even if you have signed a consent form. You don't have to give a reason for refusing or withdrawing, though it may help the researchers if you do as it might be something they can change or improve in future.

■ What will happen to my blood or other samples?

In law, when blood and other samples are taken for research, it must be with your agreement and you can say what you want done with them and how they can be used. You can ask for your blood and other samples to be withdrawn from the research, although in practice it is difficult to do so.

■ What happens at the end of the research?

If you receive a medicine or treatment that helps you, you may want to ask what will happen at the end of the study.

- If the new treatment helps me, can I continue with it after the study ends?
- Will I have any medical checks later on to see if a new treatment has had side-effects which only show, perhaps, years later?

■ Is the study a randomised controlled trial?

A randomised trial is a trial that compares two or more treatments. A computer usually decides the treatment you receive at random. This is to make sure that treatments are compared in a fair way and that everyone taking part has an equal chance to try each type of treatment.

In a **blind trial**, you do not know which treatment group you are in. In a **double blind trial**, your doctor will not know either. Only some of the researchers will know. This helps to stop one group of people doing better than another simply because they believe they are having the best treatment.

If you are invited to take part in a randomised trial, you may want to ask:

- What is each type of treatment like?
- Do I mind which treatment group I am put in?
- Do I mind treatment being chosen at random rather than by the doctor or me?

