RESEARCH · FAQs ▲

WHAT TYPICALLY HAPPENS DURING A CLINICAL RESEARCH TRIAL?

During an interventional trial you may be given a particular drug, or device, or treated using a new procedure. How you respond to this intervention will be closely monitored and recorded. During the trial you will probably need to be examined, which might involve measurements such as your weight, height or blood pressure. You may need to have blood tests and scans, to see how you react to a particular intervention. If you enquire about a trial, the research team will be able to provide you with more detail on exactly what you will need to do.

HOW LONG DO TRIALS TAKE?

The length of a particular trial or study will vary. If you enquire about a particular trial, the research team will be able to explain to you the time commitment, how long the trial will last, where it's located, how many visits you will need to make to hospital and whether you will need to stay overnight. Some studies only involve one visit and could be over in a few months, while others can continue for several years. The length of time depends upon how long it takes to identify and recruit an appropriate number of participants, how long each participant needs to spend in the study and how long is needed to follow up and analyse the resulting data.

WHAT ABOUT CONFIDENTIALITY?

If you take part in a study, people other than your doctors will need access to your medical records. However, this information is usually anonymised. Everyone who will have access to your records has to follow the same confidentiality guidelines as all other hospital staff. Sometimes the research is carried out at many hospitals and we need to share the information about how the study is progressing. If we do send out information to other organisations, your personal details will be replaced by an anonymised identification number to protect your confidentiality. All confidentiality issues will be detailed in a patient information sheet accompanying each research study, which you can read and discuss before you give your consent to participate.

HOW DO I KNOW IF I'M ELIGIBLE TO TAKE PART?

Every trial has specific eligibility criteria, which may include age, gender, your medical condition and treatment history.

WHO DOES THE RESEARCH?

This will depend on the study, but it is likely to be a combination of doctors, nurses or midwives and other healthcare professionals. Research can also involve medical students. Please feel

free to ask who is carrying out the research and who is funding the study, if this may affect your decision to take part.

WHO APPROVES THE STUDY?

All studies carried out at our Trust are approved by an independent research ethics committee and the Health Research Authority, following national procedures and guidelines. They examine everything that will take place in the study and how it will be done, with a particular focus on the interests of patients.

WILL I BE ABLE TO FIND OUT THE RESULTS OF THE RESEARCH?

The research team will be able to tell you when the project is completed and when the results will be available.

WHAT IF I HAVE CONCERNS ABOUT THE RESEARCH?

If you have any questions or concerns about the research, you should contact the research team in the first instance. If you need to take your concerns further please speak to the patient advice and liaison service (PALS) at the hospital.

WILL I HAVE TO DECIDE STRAIGHT AWAY IF I WANT TO TAKE PART?

No. It is better to take the time to discuss the benefits and the risks with other healthcare professionals (such as your GP) or with relatives or friends before you decide. The research team will also be available to discuss the study further.

WILL I BE PAID TO TAKE PART?

Some healthcare research trials pay their participants a fee to take part. Others reimburse their participants for any expenses incurred such as travel to and from hospital. It is worth discussing the financial implications of the trial with the researcher responsible for it when you enquire about taking part.

WHAT ARE THE RISKS OF TAKING PART IN A CLINICAL TRIAL?

The risks of taking part in clinical research are low due to the levels of expertise, regulation and quality assurance involved. However, in studying new treatments and investigations, our research teams may be aware of possible side effects, and will discuss these with you in advance. For earlier phase research, there is a possibility of unknown side-effects but again, this will be discussed with you, so you can make the decision as to whether the risk outweighs the potential benefits. It is important to bear in mind that many routine treatments and investigations have the potential for side effects, but these are rarely serious.

Your health will be closely monitored during a study and you will be asked to tell us about any illnesses or changes in your body that you notice.

WHAT ARE THE BENEFITS OF TAKING PART IN A TRIAL?

Research trials examine potential new treatments and techniques which, in the long-term, could help to cure or control a particular health condition. Dependent on the condition you are suffering from, the trial you take part in could help to improve your symptoms. By taking part in healthcare research you may have access to new drugs and techniques that are not yet licensed or available on prescription. You will be supported throughout your trial and have regular access to healthcare professionals and experts.

Many people participate in studies from an altruistic perspective. They understand that while the research trial they are taking part in might not make a difference to their prognosis or symptoms, it may help sufferers of a particular condition in future generations. They are happy to be able to support the advancement of healthcare and the development of new techniques and therapies.

CAN I WITHDRAW FROM THE TRIAL AT ANY TIME?

Yes you can withdraw from a clinical research study at any time, without giving a reason, and your ongoing treatment and care will continue as normal.

MY FIRST LANGUAGE ISN'T ENGLISH – DO YOU PROVIDE INTERPRETATION?

Yes, study documentation such as patient information sheets can often be translated into a number of other languages.

QUESTIONS FOR YOU TO ASK THE RESEARCHER OR PRINCIPAL INVESTIGATOR:

-What are the aims of this particular research study/trial?

- What will happen to me during the trial? (e.g. what medical interventions will I receive or what additional tests/measurements will I be required to contribute?)
- Will I receive any reimbursement or payment for the trial? Will there be any upfront costs, e.g. parking?
- How long will the study/trial last and what is the time commitment?
- Who is the principal investigator?
- Who are you likely to see during the research study/trial?
- What happens after the study/trial?

OTHER PARTNERS

GHNHSFT RESEARCH INNOVATION FORUM

The Forum is responsible for Quality Committee for the following main functions:

- To develop and regularly refresh the research and innovation strategy
- To identify approaches to increase the participation of staff in high quality research and innovation that increases the income to the Trust and meets the requirements of the DH research governance framework
- To identify approaches to increase the accrual of patients into portfolio studies.
- To monitor the performance of GHNHSFT in relation to, accrual, approval and income related activity
- To monitor the performance of the GHNHFT to determine appropriate allocation from the Research Forum budget

RESEARCH 4 GLOUCESTERSHIRE

The University of Gloucestershire, Gloucestershire Hospitals NHS Foundation Trust, 2gether NHS Foundation Trust, Gloucestershire Care Services NHS Trust, Gloucestershire Clinical Commissioning Group and Gloucestershire County Council Public Health, Social Services work in partnership to promote and undertake research which will benefit health and care services in Gloucestershire.

Working together to:

- Identify and pursue research themes and issues of common interest
- Use research to inform improvements in patient care and service delivery
- Improve access to research focused funding bodies and grants
- Pool resources and develop transferable skills between staff.