

Guy's and St Thomas'

NHS Foundation Trust

A young boy with dark, curly hair is sitting in an orange chair in a hospital room. He is looking down at his arm, which has a white bandage. A healthcare professional's hands are visible, one holding the boy's arm and the other applying the bandage. In the background, there is a grey medical cabinet and a blue balloon with colorful streamers.

Taking part in
medical research studies



"Medical research studies depend very much on the local and wider community because they require their active participation."

Professor Gideon Lack, Head of Children's Allergy Service

Getting involved

Guy's and St Thomas' hospitals have a long tradition of making significant medical breakthroughs and developing new treatments.

With our university partner, King's College London, we are a major centre for NHS-funded research. We are one of only five National Institute for Health Research comprehensive Biomedical Research Centres in England and one of the UK's first Academic Health Sciences Centres, known as King's Health Partners. These pioneering collaborations bring together excellence in health care, research and education.

Organisations like ours that are involved in research, and which offer their patients the chance to take part in clinical trials, are generally those that provide the latest and best available treatment. There is evidence that for some conditions patients on clinical trials have better long term outcomes, and may also get earlier access to new drugs.

With a large and ethnically diverse population on our doorstep, we have an exciting opportunity to lead research into a wide range of diseases. We depend on the willingness of patients and healthy volunteers to participate in the medical studies taking place at our hospitals.

When you or your child come to one of our hospitals, either as an inpatient or for an outpatient or day case appointment, you may be invited to take part in a research study. It is entirely up to you whether or not you wish to get involved. If you decide not to participate, this won't affect your treatment in any way.

This booklet aims to answer your questions about medical research to help you decide whether or not you want to get involved.

What is medical research?

Medical research has a number of aims:

- to improve our understanding of the causes and development of medical conditions;
- to prevent illnesses and reduce the number of people who become ill;
- to find new ways to treat diseases and improve the quality of life for people living with them;
- to develop new treatments and medicines.

We hope that research carried out in our hospitals will not only improve care for our patients, but will also benefit others in this country and further afield.

"If my participation now helps someone else in 20 years time then I am happy to make that contribution."

A Diabetes type 1 patient

Why is medical research important?

Without it, there would be no new medicines or tests, improved treatments, or better ways of providing healthcare. Some treatments developed over the last few decades have led to improved rates of survival for major health problems. For example, a clot busting injection, streptokinase, can reduce sudden deaths after a heart attack by a quarter. The use of tamoxifen in breast cancer has led to a 20-30 per cent improvement in survival rates.





What are the different kinds of research?

There are many different kinds of medical research. Two that are very important within our hospitals are:

1 Research involving cells and tissue

Cells are the basic units which make up our bodies and perform all of the functions we need.

Cells can work as single units or can form tissues. In tissues, different cell types come together to carry out a particular job for your body, for example they may form muscles to produce force and motion.

Human cells and tissue are vital for medical research. They can be collected during many routine procedures, including:

- blood tests;
- operations;
- biopsies (tissue samples taken for examination).

Researchers can use these cells and tissues to learn about how diseases start and then develop, and also how new drugs and tests might work before clinical trials begin.

2 Clinical trials

Clinical trials are research studies that involve patients or healthy volunteers and are designed to test new treatments.

Treatments could include new drugs, vaccines, other approaches to disease prevention, surgery, radiation treatment, physical and psychological therapies, educational programmes or methods of diagnosing disease. They could also include disease prevention.

Involving people in clinical trials allows us to see whether the new methods are effective and safe. Trials are very carefully planned and regulated to ensure that patient safety is at their heart.

Not everyone receives a new treatment in a clinical trial, as we often need to compare a new treatment with a standard treatment already in use, or with a 'dummy' treatment known as a 'placebo'. In many studies, patients are selected randomly, by a process like flipping a coin, to receive a new, a standard, or a dummy treatment. It is often important that the participants and researchers don't know who is receiving which treatment until the study is finished.

The outcomes of clinical research help the NHS decide which treatments are most effective and which give the greatest benefit.

What do I have to do?

Your involvement, and the time that each study takes, will vary depending upon what is being investigated.

The information given to you by the research team will include details of the estimated length of the study and what will be expected of you. If there is anything you do not understand you should ask the researcher to explain it to you.

If you are happy to get involved in a research study you will need to give informed consent, to show that you understand what is being asked of you and to confirm you agree to take part. You should not give your consent if you are unclear about any aspect of the research.

What are the benefits of taking part?

If you take part in a research study, you will have more contact with medical staff than you normally do and there will be opportunities to gain information about your medical condition, which may help you to manage it better.

In many cases, the research will not help you personally, but it may provide vital information that will help people in the future. This will be explained to you.



Who approves the study?

Research studies are carefully designed by doctors and researchers, often with input from patients.

Before any study begins, it must be approved by a Research Ethics Committee – a panel of health and social care professionals and members of the public with knowledge of, and/or an interest in research. They consider all aspects of the study, including patients' welfare and interests. No medical study is carried out in our hospitals without ethics committee approval.

What are the risks?

When a research study is designed, every effort is made to eliminate any risk to patients, and the ethics committee will also check this.

Each study will be different and so the risks will vary. Any known risks will be explained to you.

The doctors and nurses responsible for the research will monitor participants very carefully to detect any side effects and changes. If there are changes, medical staff will act immediately. If you are taking part in a research study, it is important to tell us about any illnesses or changes in your body that you notice.

Is my information confidential?

When taking part in a research study, people other than your doctor will need to see your medical records. However, everyone who sees your records will follow the same confidentiality guidelines as all other hospital staff, in accordance with the Data Protection Act.

Sometimes research is carried out nationally across several hospitals or even internationally and we need to share the information about how the study is progressing. If we send information to other researchers, your personal details will not be included to protect your confidentiality.

Who does the research?

This will depend on the study, but it is likely to be a combination of doctors, nurses, and other healthcare professionals. Research may also be done by students under supervision. You will be told who will do the research and who is funding it.

“Why did I get it now? I’m young and healthy. For me, if there was an opportunity to go on any sort of drugs trial, I would do it.”

A young woman diagnosed with Triple Negative Breast Cancer

Will I be able to see the results?

The researcher should tell you when the research is complete and the results are available.

Results should always be made public and this may include articles in medical journals or on websites. Some researchers also create a participant’s version of the results and you should ask your research team about this if you are interested. Findings from research studies are often also publicised in the media.

What if I have concerns?

If you have any concerns you should raise these with a member of the research team as soon as possible, or contact the Patient Advice and Liaison Service (PALS) at the hospital for advice. Please see the back page for contact details.

Never feel embarrassed to ask questions as we want to support you, and it may also help us to improve future studies.

Questions to ask?

We advise you to take your time deciding whether or not to take part in a research study and to discuss your participation with other healthcare professionals, such as your GP, or with relatives and friends.

If you agree to take part, the researchers will ask you to sign a consent form. Here are some questions you may want to ask before you do.

What is the aim of the study?

How/why was I chosen?

Is the research a clinical trial to test a new treatment?

What are my treatment options?

Does the research involve collecting samples of my cells or tissues?



Who is paying for the research?

Is my treatment affected if I don't get involved?

How long will the research take and what will I have to do?

What will happen to me? Will I have tablets or injections?

What will be different to the treatment or care I would normally receive?

If you are testing a new drug, how many people have taken it before?

What are the possible side effects of the new treatment or procedure?

What happens if something goes wrong?

Would I get compensation if taking part in the research study harms me?

Who can I talk to if I have any questions, concerns or problems?

If tissue or other samples are taken, what will happen to them and can they be used in other research projects?

If I change my mind, can I leave the study once I have started?

Will I need to take time off work?

Will I receive any payment for my time/travel expenses?

Further information

PALS – To make comments or raise concerns about the Trust's services, please contact our Patient Advice and Liaison Service (PALS). Ask a member of staff to direct you to PALS or:

t: 020 7188 8801 at St Thomas' **t:** 020 7188 8803 at Guy's
e: pals@gstt.nhs.uk

Knowledge & Information Centre (KIC) – For more information about health conditions, support groups and local services, or to search the internet and send emails, please visit the KIC on the Ground Floor, North Wing, St Thomas' Hospital.
t: 020 7188 3416 **e:** kic@gstt.nhs.uk

Language Support Services – If you need an interpreter or information about the care you are receiving in the language or format of your choice, please get in touch using the following contact details.

t: 020 7188 8815 **f:** 020 7188 5953
e: languagesupport@gstt.nhs.uk

NHS Direct – Offers health information and advice from specially trained nurses over the phone 24 hours a day.
t: 0845 4647 **w:** www.nhsdirect.nhs.uk

Contact us

For more information about our services
visit the Trust website

www.guysandstthomas.nhs.uk

**Guy's and St Thomas'
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St Thomas' Hospital
Westminster Bridge Road
London SE1 7EH

Guy's Hospital
Great Maze Pond
London SE1 9RT

Switchboard: 020 7188 7188