ST. JAMES'S HOSPITAL

Trinity College Dublin
Coláiste na Tríonóide, Baile Átha Cliath
The University of Dublin

Patient Information Leaflet

Clinical Research

Phone: 01 4103904 / 01 410 3021
E-mail: research@stjames.ie / dataprotection@stjames.ie

What is clinical research?

Clinical research has the potential to help us expand our knowledge of human diseases, to prevent and treat illnesses and to promote health and improve patient care. St James's Hospital works together with its **academic partner,** Trinity College Dublin to deliver high quality research studies to our patients.

Doctors, scientists and other healthcare professionals such as physiotherapists and dieticians, participate in research with the aim of improving patient care. Some research studies are led by the Hospital, others are led by Trinity College Dublin and others have commercial sponsors. You can find out more about this in the research study's patient information leaflet.

Why is clinical research important?

Clinical research is important to us in St James's Hospital because it aims to improve the **quality and efficiency** of our health services, and enhance the **quality of life** of patients. It helps us to find new and better ways to detect, prevent, diagnose, and treat disease. Clinical research would not be possible without the participation of our patients. We hope this leaflet will help you to understand what research is all about. **Ask your doctor** for more information about research studies that you may be able to take part in.

Safeguards before the research begins

All clinical research studies are reviewed by an **Ethics Committee.** The committee will give an opinion about whether the research is ethical. This helps to safeguard the dignity, rights, safety and well-being of research participants. Clinical research studies are also **reviewed by the Hospital** before they are given permission to begin.

What is pre-screening?

Pre-screening involves looking at patient healthcare records in order to find out whether a person may be suitable to take part in a research study. This is carried out by hospital employees or other hospital approved researchers. You do not need to give consent for pre-screening; however, if you might be suitable to participate in a research study, the research team or your doctor will contact you to ask if you would like to receive more information and to take part. Pre-screening helps to ensure that only patients who are likely to meet the study requirements are approached about the research study.

Consent for clinical research

You will always be asked to give your consent before entering into a research study – with the exception of retrospective chart review research which is explained below. You will be given an information leaflet about the study which will explain what the study involves and how your information will be used. You will be provided with the time to read the leaflet and have your questions answered before you are asked to sign a consent form.

Your participation is always voluntary and you can stop taking part in the research study at any time. It will not affect your current or future medical care in any way if you decide not to take part in the research.

Retrospective chart review research

This is when healthcare professionals, for example doctors or nurses, look back at existing healthcare records with the aim of learning more about a disease or condition. This type of research does not involve any intervention, but it is extremely important, as it may inform and improve future patient care. Consent is not required for this type of research. Research results are only shared in aggregated and anonymised form through reporting, publications and at conferences. Your personal information will be protected and will not be identifiable in the final results.

Is my information safe?

St James's Hospital and Trinity College Dublin are committed to ensuring the privacy and confidentiality of your personal information.

All researchers conducting clinical research will sign a confidentiality agreement before accessing any personal information, and only information relevant to the study is released to researchers. All clinical research is carried out in compliance with General Data Protection Regulations (GDPR), part of EU-wide law to protect your data privacy. The research must also be approved by the Research Ethics Committee and the Hospital. Researchers will complete a Data Protection Impact Assessment (DPIA) form before the research begins – this will help to identify and reduce any data-related risks.

What types of Clinical Research are conducted in the Hospital?

There are many types of clinical research studies happening in St James's Hospital, examples are:

- **Clinical trials:** a form of research used to test new treatments for diseases.
- **Clinical research using patient samples (blood, urine, stools, hair, tissue etc):** normally takes place in the laboratory and aims to answer questions such as; what triggers the onset of an illness and what is the best way to treat an illness? One example where you may be asked to donate a sample is for the St James's Hospital **Biobank,** this is a large collection of donated patient samples which are then used in various research studies.
- **Observational studies:** participants are followed up by the research team over time, either by phone or in person, depending on the type of research study. This type of research can be used to find out more about risk factors for diseases.
- **Research using patient medical records (retrospective chart reviews):** this research looks back in time at patients' medical records with the aim of learning more about a disease or condition.

We welcome your feedback

If you have any queries or feedback on the content of this leaflet please do not hesitate to contact us by telephone, email or by adding comments below and returning it to us.

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