Clinical Research and Data Protection

Tallaght University Hospital and our academic partner Trinity College Dublin are committed to protecting the confidentiality and privacy of all our patients.

All clinical research is carried out in compliance with data protection legislation and is approved by the Research Ethics Committee.

All researchers must complete Good Clinical Practice training to ensure they know how to perform clinical research to a high standard and Data Protection training to ensure they know how to protect your data when performing Clinical Research.

Further Information

Please see privacy notices positioned at registration points around TUH for more details.

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

Tallaght University Hospital | Ospidéal Ollscoile Thamhlachta

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Clinical Research at Tallaght University Hospital

Information for Patients

What is Clinical Research?

Clinical research is the study of patients, their personal medical data and/or their samples (blood, urine, stool, hair, tissue, etc) through either direct contact with the patient or indirectly using medical notes.

The aim of clinical research is to advance medical knowledge, the skills of health care practitioners and the quality of the medical service Tallaght University Hospital can offer to patients.

Clinical research helps use to find new and improved ways of detecting, diagnosing, treating and preventing disease.

Tallaght University Hospital's academic partner is Trinity College Dublin. Researchers from the hospital, who include your doctors and nurses work in partnership with researchers from Trinity College Dublin in order to bring high quality research to the patients of Tallaght University Hospital.

The Research Ethics Committee at Tallaght University Hospital is a joint committee with St James's Hospital. The Joint Research Ethics Committee is composed of hospital consultants, nurses, GPs, other healthcare providers and lay people who's job it is to review the studies proposed to take place in Tallaght University Hospital and St James's Hospital in order to determine if the study is ethically sound and safe for patients to take part in. This process helps to safe-guard the dignity, rights, safety and well-being of research participants.

Types of Clinical Research

There are many different types of clinical research studies taking place in Tallaght University Hospital, some examples are:

- **Clinical Trials** – this is a study conducted to test if a new drug is effective at treating a specific disease.
- **Clinical Research Utilising Patient Samples** – some studies involve looking at patient samples in conjunction with the medical data associated with the sample.
- **Observational Studies -** these studies involve the observation of patients over a period of time and may include the collection of samples.
- **Research Using Patient Medical Records (Retrospective Studies)** – these studies involve looking back at patients medical history with the aim of learning more about the disease or condition, an example would be to determine the number of people with a certain disease or the average age of onset of a particular disease.

Clinical research is a vital part of the health service. Without clinical research no new treatments would be discovered

When is your medical data used for clinical research?

Following your consent – for clinical trials, clinical research using your samples and observational studies your consent will be sought before proceeding with the research. You will be provided with an information leaflet which will outline the study. If you agree to take part you will give your consent by signing a consent form and agreeing to all aspects of the research on the study consent form .

Pre-screening – pre-screening is the process researchers use to identify patients that may be suitable for the research study they wish to undertake. This involves accessing medical records for the purpose of identifying patients but no data is removed/copied/recorded. This is only done by healthcare practitioners, student healthcare practitioners within TUH and hospital employees who normally have access to medical records. You will not be contacted to give your consent for pre-screening, however, should you be deemed suitable you will be contacted in order to provide you with information about the study and if you feel comfortable and happy, to obtain your consent. TUH do not currently allow authorised persons to access charts for pre-screening purposes

Research using patient medical records (Retrospective studies) – is a type of research design in which pre-recorded, patient-centred data collected for the provision of healthcare are used to answer a research question. Consent is not sought for this type of study BUT only when the study meets certain criteria**:** (i) the data is protected by a unique coding system. This means your name and any other information that could identify you will never be stored with the medical data collected (ii) a data protection impact assessment has concluded that the study is low risk (iii) it is performed by a healthcare practitioner who is an employee of TUH or a student healthcare practitioner (iii) or another employee of TUH who in their normal duties has access to medical records (iv) the data will not be shared unless completely anonymous (v) the published results will not identify any individual and (vi) the Research Ethics Committee must review and approve. If a study does not meet this criteria your consent will be sought.