Our Lady's Hospice & Care Services

Data Protection & Research Guidelines:

Definition of Health Research –

Research with the goal of understanding normal and abnormal functioning, at the molecular, cellular, organ system and whole body levels;

Research that is specifically concerned with innovative strategies, devices, products or services for the diagnosis, treatment or prevention of human disease or injury;

Research with the goal of improving the diagnosis and treatment (including the rehabilitation and palliation) of human disease and injury and of improving the health and quality of the individuals;

Research with the goal of improving the efficiency and effectiveness of health professionals and the health care system;

Research with the goal of improving the health of the population or of defined sub-populations through a better understanding of the ways in which social, cultural, environmental, occupational and economic factors determine health status;

And *MAY* include a necessary action taken to establish whether an individual may be suitable for inclusion in the research.

Research is…

Research is designed and conducted to generate new generalizable or transferable knowledge

It includes both quantitative and qualitative studies that aim to generate new hypotheses as well as studies that aim to test existing or new hypotheses.

Research isn't…

Service evaluation – assess choices of treatment, care or services that are currently available according to guidance, professional standards, and/or patient/service user preference;

e.g. evaluations performed to assess current care of a patient; evaluations of the standard of care a service achieves; evaluations aimed at determining or choosing appropriate treatment or service options.

Clinical Audit – does this service reach a pre-determined standard?

It measures the delivery of an intervention against a standard.

e.g. evaluations designed to inform best service or care delivery; evaluations of whether or not a care or service meets required standards; evaluations relating to current treatments or interventions.

What is Data Processing?

Data processing includes, for example, any operation or set of operations performed on personal data, collection, recording, organising, structuring, storage, retrieval, alteration, erasure, destruction.

Identify the Data Controller and Processor

Who is the controller?

A data controller determines the purposes, conditions, and means of the processing of personal data.

There may be joint controllers or more than one controller.

The controller is responsible for ensuring compliance with the principles of GDPR.

In practice, to identify the data controller, as the following questions –

Who is deciding <u>WHY</u> (the purpose) personal information is going to be processed? i.e. a study to investigate medication compliance.

Who is deciding <u>HOW</u> (means and conditions) the personal information is to be processed?, i.e. the manner in which the research is going to be conducted. Project design.

OLHCS is a joint controller if with one or more organisations we jointly determine **Why** and **How** data should be processed.

If OLHCS is a joint controller, we must enter an agreement setting out responsibilities for complying with GDPR.

A data processor processes personal data on behalf of the data controller.

Examples of data processors include –

Payroll companies or accountants or similar who hold and process personal information on behalf of someone else;

'Cloud' providers are also generally data processors;

If you hire a third party to process data for your research (e.g. a transcriber), the third party will be a data processor.

A data processor **does not include** the employees of a Data Controller (e.g. researchers employed on research projects in which personal data is collected, processed and stored).

If you are a researcher, you might be a data processor if you are employed on a service contract that collects, stores or processes personal data on behalf of a Data Controller.

A **Data Processor Agreement (DPA)** should be in place.

The agreement should set out:

- The terms of the agreement;
- Regulatory compliance;
- Obligations of the data controller;
- Right of audit;
- Data subject rights;
- Liability and indemnity;
- Law applicable to the agreement;
- Resolution dispute with Data Subject or DPC;
- Termination and variation of the agreement.

An example,

Medical Records – OLHCS is a data controller of medical records relating to our patients

As part of research studies, it is often necessary for the research team acting on behalf of their academic sponsor to access information for research purposes.

The academic sponsor does, and should, get consent from the study subjects before doing so, and on that basis, the academic sponsor accesses this data in its own data controller capacity, i.e. as a separate data controller and not as a joint controller.

An example

Research collaboration between two academic partners where both the academic partners would be acting together to determine the purposes and manner of data processing of data.

In this instance the academic partners may be considered to be joint controllers.

An example

OLHCS is gathering patient data in the form of medical charts as part of direct care.

OLHCS is the Data Controller.

Role of Data Protection Officer

The Controller and Processor shall ensure that the DPO is involved properly and in a timely manner, in all issues relating to data protection;

The DPO shall inform and advise the Controller or Processor of their legal obligations;

The DPO shall monitor compliance;

The DPO shall provide training and policies;

The DPO shall provide advice regarding Data Protection Impact Assessments.

Know your Data

Identifiable Data – is the data subject identifiable?

Pseudonymised Data – data that can no longer be attributed to the data subject without additional information which is kept separately.

Anonymous – data which can no longer be attributable to the data subject.

Identifiable and Pseudonymised data falls under GDPR.

Anonymised data falls outside the scope of GDPR.

Know your lawful basis for processing

This is your valid legal reason to process and use data under GDPR.

Article 6 provides 6 legal basis for processing Personal Data.

Article 9 provides 10 legal basis for processing Sensitive Personal data.

You must pick one legal basis from Article 6 when processing personal data and an additional legal basis from Article 9 when processing sensitive personal data.

You must have two legal basis for processing sensitive personal data.

Article 6 – Lawful Basis

For public authorities such as universities, HSE etc. the most relevant legal basis for research under Article 6 will be:

Article 6(1)(e) Processing is necessary for the performance of a task carried out in the public interest.

If using this, you must document justification by referencing the public research purpose of the authority as established by charter or statute.

Commercial companies and charitable organisations such as OLHCS will most likely continue to use Article 6 (1) (f) Legitimate Interests.