CRFG
HRB Clinical Research Facility, Galway

Personal Data Privacy Statement

What is GDPR?
The General Data Protection Regulation (GDPR) comes into effect on the 25th May 2018 across the European Union, replacing the previous data protection framework under Irish and EU legislation. Its main focus is to strengthen data protection rights for individuals when it comes to the processing of their personal data within the European Union. It will provide a framework with greater scope and much tougher punishments such as large fines for those who fail to comply with these new rules around the storage and handling of personal data that may be collected by companies or organisations.

What is Personal Data?
Personal data is defined in Article 4 of GDPR as:

"means any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person."

The CRFG conducts clinical research using personal data in the form of health information collected from patients who have consented to take part in a clinical trial.

What is the CRFG?
The Health Research Board (HRB) Clinical Research Facility, Galway (CRFG) is a purpose built, state of the art clinical research centre based on the grounds of Galway University Hospitals and co-governed by NUI Galway and UHG. It conducts high quality clinical research from early phase clinical trials right through to population health research. The CRFG conducts clinical research in accordance with ICH- Good Clinical Practice (GCP) standards which is an international minimum quality standard for the ethical and scientific conduct of clinical research. The CRFG contributes to clinical research by supporting investigators and research teams (from HSE, NUI Galway, academics from other institutions or industry) in undertaking research projects and programmes by providing services such as research nursing support, pharmacy services and data management, with a robust quality oversight.

What function does the CRFG fulfil with respect to GDPR?
Under GDPR, the CRFG is considered as a service provider (i.e. "any agency, practice or organisation proposing to undertake a project involving the collection of personal health information"). The CRFG conducts clinical research which requires the collection, management, storage and processing of personal data from patients (data subjects or service users) who participate in clinical trials or studies at our site.

How is data typically collected by the CRFG?
In the CRFG your data is gathered by Data Processors who are typically members of the Study Research team for your study (e.g. Clinical Research Assistants, Clinical Research Associates, Clinical Research Nurses, Investigators, Pharmacists). Data is processed in adherence to the processes outlined by the Data Controller (Sponsor, Principle investigator); in accordance with the requirements of the internal CRFG quality system policies and procedures and applicable standards, legislation and regulation for the conduct of clinical research (ICH-GCP, ISO14155 and applicable EU legislation pertaining to the conduct of Clinical Research and the requirements of GDPR).

What Personal Data is used in Clinical Research?
The following are some examples of personal data that may be collected as part of clinical research at the CRFG:

- Contact details of the research participant and where applicable, next of kin, relatives or professional caregivers.

Personal Data Privacy Statement

- Bank details for participant reimbursement.
- Medical information collected for the purposes of research and for clinical care
- Socioeconomic information collected for the purposes of research or clinical care

What is the legal basis for collecting personal data at the CRFG?

Data gathered by the CRFG is for clinical research, which provides the legal basis for its collection. We use your information (the data subject/service user) for the purpose of clinical research only after you have provided explicit, informed consent that you are willing to participate in a clinical trial/study. As per Article 6, providing written informed consent gives the CRFG the lawful basis to process your personal data for specific purposes stated in the clinical trial or study. The characteristic of the written informed consent process, laid down in ICH-GCP, is in line with the requirements of written informed consent per GDPR.

What rights does GDPR provide?

GDPR ensures the rights of the individual are protected. These include your right, at any time, to withdraw your consent (also known as "Right to object" Article 21 under GDPR) from continuing in the clinical research study. Additionally, under GDPR, you have the following enhanced rights in relation to how we use your personal data:

- **Right of access –** you have the right to request a copy of the information that we hold about you. (Article 15)
- **Right of rectification –** you have a right to correct data that we hold about you that is inaccurate or incomplete. (Article 16)
- **Right to erasure –** in certain circumstances, you can ask for the data we hold about you to be erased from our records. (Article 17)
- **Right to restriction of processing –** where certain conditions apply to have a right to restrict the processing e.g. transferring data to third parties. (Article 18)
- **Right to data portability** – which means you have the right to receive your personal data in a structured, commonly used and machine-readable format with the aim of transmitting that data to another controller (e.g. organisation/hospital/research body) without hindrance. (Article 20)
- **Automated individual decision making**- the right not to be subject to a decision based solely on automated processing. This should be detailed in any information given to you during informed written consent prior to participating in any clinical research. (Article 22)

Sharing of your data by the CRFG is restricted:

Your data is protected as per the requirements of applicable standards, legislation and regulation for the conduct of clinical research; ICH-GCP, ISO14155 and applicable EU legislation pertaining to the conduct of Clinical Research and the requirements of GDPR. We only share your information as necessary in line with the requirements of the study to facilitate the conduct of the research and to ensure your safety and protection. Those with whom we are likely to share your information will be outlined in the participant information provided prior to participation in a study and may include:

- Data processors who are delegated the task of managing the data by the Controller,
- The Ethics committee appointed for the Study,
- The Data Safety Committee or Monitoring Board appointed for the Study if applicable,
- The Competent Authority (HPRA –to facilitate during audit and inspection)
- The Data Controller of the study.

Any transfer of personal data to third parties or countries outside EU will be stated in the information provided (informed consent process) prior to participating in the clinical trial/study. The organisation or individual running the trial (known as Sponsor of the study and the Principal Investigator) must inform you of any changes in relation to the transfer of your data

Personal Data Privacy Statement

prior to processing it so that your privacy rights are protected under Article 18 GDPR 'Right to restriction of processing' and is responsible for ensuring that the appropriate security measures are implemented such that any potential risks for the data subject are mitigated to an acceptable level prior to execution of a Data Transfer.

For how long is your data retained by the CRFG?

This will be stated in the information provided to you at the time of consent to participate in the clinical trial/study. The retention of Clinical Research Data is in accordance with at least the minimum duration outlined in the applicable standards, legislation and regulation for the conduct of clinical research; ICH-GCP, ISO14155 and applicable EU legislation.

How does the CRFG protect your personal data?

In preparation for GDPR on May 25th 2018, the CRFG has undertaken a number of steps to ensure compliance with the new rules but also to ensure that your personal data and privacy rights are respected and protected throughout our daily processes and systems.

A project team was set up consisting of senior management staff with the task of reviewing current internal polices to ensure they are aligned with GDPR. Information sessions and training were organised to spread awareness of GDPR within the organisation to prepare staff for the new regulation requirements from 25th May 2018. This will remain an ongoing internal quality assurance process that will be reviewed regularly and evolve as needed.

How to contact us and/or the CRFG Data Protection Officer:

If you have any questions regarding GDPR or specific personal data you believe or know the CRFG holds you may contact:

- Study queries or to speak with study lead:
  - T: 091 494 369.
- NUI Galway Data Protection Officer:
  - dataprotection@nuigalway.ie
- HSE West & South Deputy Data Protection Officer:
  - ddpo.west@hse.ie / T: 091 775819

In the event that you wish to make a complaint about how your personal data is being processed by us or how your complaint has been handled, you have the right to lodge a complaint directly with the supervisory authority:

Data Protection Commissioner

- Office of the Data Protection Commissioner. Canal House, Station Road, Portarlington, Co. Laois, R32 AP23, Ireland.
- Phone +353 (0761) 104 800
- LoCall 1890 25 22 31
- Email info@dataprotection.ie

More information

For further detailed information regarding GDPR please refer to:

https://dataprotection.ie/docs/A-guide-to-your-rights-Plain-English-Version/r/858.htm