Cancer Biobank Personal Data Privacy Statement

What is GDPR?

The European Union General Data Protection Regulation (GDPR) came into effect on the 25th of May 2018, replacing the previous data protection framework under Irish and EU legislation. Its focus is to strengthen data protection rights for individuals when it comes to the processing of their personal data within the European Union. It provides 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.
More Information: https://dataprotection.ie/en

What is Personal Data?

Personal data is defined in Article 4 of GDPR as:

"any information relating to an identified or identifiable natural person ('data subject'); and 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 Cancer Biobank collects and processes personal data in the form of biobank sample-related data and health information collected from consenting participants.

What is the Cancer Biobank?

University of Galway in partnership with Saolta University Health Care Group (Saolta) conduct health research that aims to identify markers to better predict how cancer develops, progresses, and responds to treatment. The Cancer Biobank is a long-term translational research resource of human biological samples and associated personal and health-related data. Cancer Biobank pseudonymised data and samples are only made available to research collaborators who have received ethical approval for their studies.

What is the function of the Cancer Biobank with respect to GDPR?

Under GDPR, HSE Saolta and the University of Galway are joint data controllers. A data protection impact assessment (DPIA) and joint controller agreement (JCA) are in place for HSE Saolta and University of Galway. The Cancer Biobank is a resource for translational cancer research which requires the collection, management, storage, and processing of personal data from Cancer Biobank participants (data subjects).

How is data typically collected by the Cancer Biobank?

Your personal data will be gathered and processed under a Data Processing and Confidentiality Agreement which regulates University of Galway and its representatives as the Data Processor, in the processing of personal data. Authorised Cancer Biobank personnel collect identifiable information provided on the sample form which is completed by your clinical team and received with your biobank sample. This data is entered onto the Cancer Biobank database. Additional clinical information from your medical records, both hard copy and electronic are accessed by authorised Cancer Biobank personnel. Relevant medical record data is then entered into a linked secure database categorised in accordance with your reason for referral to the hospital.

What Personal Data is used in Cancer Biobank-related research?

Personal data that may be collected as part of biobank participation and related cancer research, includes identifiable information such as: name, date of birth, address, board number, hospital number, consultant, procedure and specimen related details.
In addition, medical information such as: risk factors, family history, medical history, lifestyle data, procedures, histology, staging, laboratory test results, radiology, prognostic indices, genetic data (Special Category Data), treatment, disease progression, and survival data may be collected.

What is the legal basis for collecting Personal Data?

We use your information (the data subject) for the purposes of biobanking and cancer research. The legal basis for this is that processing is necessary for the purposes of the legitimate interests pursued by the Controller pursuant to article 6(1)(f) of GDPR and for reasons of public interest in public health pursuant to Article 9(2)(j) of GDPR.
More Information: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679&from=EN

What rights does GDPR ensure?

GDPR ensures that 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 participating in the Cancer Biobank. Additionally, under GDPR, you have the following enhanced rights in relation to how your personal data is used:

- **Right of access** – you have the right to request a copy of the information that held about you (Article 15).
- **Right of rectification** – you have the right to correct data that is held about you that is inaccurate or incomplete (Article 16).
- **Right of erasure** – in certain circumstances, you can ask for the data held about you to be erased from Cancer Biobank records (Article 17).
- **Right to restriction of processing** – where certain conditions apply, to have the right to restrict the processing e.g. transferring data to third parties (Article 18).
- **Right to data portability** – 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

(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 the biobank (Article 22).

Transfer of personal data is restricted.

Your personal data is only distributed as necessary, in line with the requirements of the cancer research study. Those with whom the Cancer Biobank are likely to provide your data with are outlined in the participant information leaflet provided prior to participation in the Cancer Biobank and may include:

- Data Controller of the Cancer Biobank,
- Data Controller of a cancer research study,
- Data processors who are delegated the task of managing the data by the Controller.

Any transfer of personal data to third parties or countries outside EU will be stated in the and information provided (informed consent process) prior to participating in the biobank. The Cancer Biobank or Principal Investigator conducting the cancer translational research study must inform you of any changes in relation to the transfer of your data prior to processing it so that your privacy rights under Article 18 GDPR 'Right to restriction of processing' 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 the Data Transfer.

How long is your data kept by the Cancer Biobank?

The Cancer Biobank is a long-term resource to be used for cancer research studies. Sample data will be retained by the Cancer Biobank for a period defined by the bio-integrity of the sample or until the sample is exhausted. After this, the specimen is recorded as exhausted, its biobank storage data recycled, and its data excluded from biobank data processing. Associated data subject data will be retained indefinitely as a valuable resource supporting cancer research. The Cancer Biobank data subject data will be pseudonymised to protect the data subject's identity. Data will not be completely anonymised as it is important to maintain a link between samples and data. Data associated with research studies will be retained for the duration of the study after which the data will be destroyed or anonymised in accordance with the study protocol.

How does the Cancer Biobank protect your data?

The Cancer Biobank takes many steps to make sure your confidentiality is protected, and your data kept safe. Here are some examples of how this is done:

Access to the Cancer Biobank Database, located on a HSE secure server, is restricted to authorised Cancer Biobank personnel only. The pseudonymisation process, whereby a unique code is assigned to your personal data, ensures that your identity remains confidential. All data files containing your data are encrypted using password protection.

A HSE Data Protection Impact Assessment is conducted for all Cancer Biobank related data processing in consultation with the HSE West Deputy Data Protection Officer and University of Galway Data Protection Officer and a resulting low level of risk identified. Your name or identity will not be disclosed, presented, or published as a result of any cancer research study.

The University of Galway Data Controller (Director of the Cancer Biobank) is bound by a professional code of secrecy in relation to your personal data. The University of Galway Data Processors are bound by the Data Processing and Confidentiality Agreement. Translational Cancer Research Teams are bound by a Cancer Biobank Data Protection Policy Agreement. All authorised Cancer Biobank personnel and research teams are trained in Data Protection Law and Data Security.

Contact Details and More Information:

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

- Cancer Biobank: www.universityofgalway.ie/biobank adminbiobank@universityofgalway.ie
- NUI Galway Data Protection Officer: dataprotection@universityofgalway.ie
- HSE West Deputy Data Protection Officer: ddpo.west@hse.ie

If 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