Ollscoil na Gaillimhe
University of Galway

Saolta
Grúpa Ollscoile Cúram Sláinte
University Health Care Group

Cancer Biobank

Participant Information Leaflet

The University of Galway in partnership with Saolta University Health Care Group (Saolta) invites you to participate in the Cancer Biobank. The Cancer Biobank is a resource of biological samples and associated data that is collected and stored for use in cancer research studies.

This information leaflet will help you decide on your participation.

We created a digital game containing all of the essential information in this leaflet. Scan the QR code to try it for yourself - it's interactive, fun and easy to use!

1. Cancer Biobank

1.1 Why do we collect samples and data for the Cancer Biobank?

Cancer is a complex disease, and affects people differently. To develop better diagnostic tests and treatments for cancer, researchers need access to biological samples. The Cancer Biobank is a resource that collects and stores samples and their associated data for use in research. Samples may be stored for several years or indefinitely, depending on the study, so that long term future research can be carried out. Researchers may track the health of the participants by looking at their past and future medical records, but only if participants have given them permission to.

1.2 Why I have been invited to participate in the Cancer Biobank?

We invite all patients who are undergoing cancer tests and/or treatment in clinics to participate. We also invite volunteers from the community to participate as non-cancer 'controls'.

1.3 Do I have to take part?

No. Your participation is entirely voluntary. If you do not wish to take part, your decision will be accepted without question and your standard of care will not be affected in any way.

1.4 What will happen if I decide to take part in the Cancer Biobank?

All samples for inclusion in the Cancer Biobank will be taken at your clinical appointment times or at arranged "control" recruitment drives. Only authorised Saolta personnel will ask you to participate in the Cancer Biobank. Staff will explain how you can participate in the Cancer Biobank and answer any questions you may have. If you wish to participate, we will ask you to carefully read and sign the informed consent form.

1.5 What type of samples and/or data are collected and when are they taken?

By participating and giving your consent, you permit the Cancer Biobank to collect some, or all, of the following:

Tissue: At the time of biopsy or surgery, we ask that you donate a small piece of your tissue. This process should not interfere with your diagnosis or treatment.

Blood: We are asking you to donate 4 tubes of blood, each containing about 5mL (1 teaspoon), in addition to bloods taken for your clinical diagnosis or treatment.

Fixed Tissue Blocks: We are asking your permission to access surplus tissue in fixed tissue blocks, which are routinely prepared from tissue taken during biopsy or resection. Once your diagnosis has been established, these blocks are routinely stored in hospital Pathology departments for future diagnostic and medico-legal purposes. The use of this surplus tissue for research will not affect your clinical care.

Other: Occasionally other types of samples may be requested. These could include saliva, buccal swabs, or urine samples depending on the needs of the research project. Follow-up samples of any of the above may be requested during your routine clinical care visit.

Data: In addition to your samples, we are asking permission to access Saolta medical record data relevant to your disease diagnosis, treatment, and follow-up.

1.6 How are my samples and data stored and what are they used for?

Your samples and associated data will be stored in the Cancer Biobank, located at the Lambe Institute, University of Galway.

The Cancer Biobank is a long-term research resource, which means that your samples and associated data will be stored until they are required for use in cancer research studies. Your pseudonymised data and samples will only be made available to research collaborators who have received ethical approval for their studies. Research may take place in the Lambe Institute or in other collaborating research institutions.

Samples: Samples are stored in ultra-low freezers (-70°C). Your sample data will be entered into the Cancer Biobank database and the Pathology database by authorised personnel. Your sample data will be 'pseudonymised' which means your samples are given a unique identification number (generated by our database software). Researchers using your samples and associated data will not be able to identify you personally.

Personal Data: Identifiable data will be stored in the Cancer Biobank database and in the Pathology database which are located on secure Saolta servers, only accessible to authorised personnel. Biobank staff have a duty of confidentiality to you as a participant - no information that could identify you will be accessible to unauthorised users.

1.7 What are the benefits of participating in the Cancer Biobank?

You will not directly benefit from participating in the Cancer Biobank. Your samples and associated data will contribute to research that could benefit patients in the future by helping to develop new tests and treatment for cancer. Your samples and associated data will not be used for commercial benefit. If knowledge gained from research leads to a commercial development, you will not benefit financially.

1.8 What are the risks to me if I take part in the Cancer Biobank?

There are no additional risks to your health by participating in the Cancer Biobank. The only (and very low) risk would be a potential loss of privacy, or data breach. Further information on data protection is detailed below in Section 3.

1.9 What happens if I change my mind? Can I withdraw?

Yes. You can withdraw from the Cancer Biobank at any time. Your withdrawal will have no impact on your clinical care. If you wish to withdraw, please inform us in writing, choosing one of the following options:

No further access: This means that the Cancer Biobank will not access your medical records any further, but will still have your consent to use the samples you already provided.

No further use: This means that samples you donated to the Cancer Biobank can no longer be used for research and will be destroyed. All remaining fixed tissue blocks will be retained in hospital Pathology departments. Your signed consent and withdrawal form will be kept as a record of your wishes.

To withdraw from the Cancer Biobank, please contact us by post or email to request a participant withdrawal form. See Cancer Biobank contact details in Section 5.2.

2. Research

By giving your explicit consent to biobank your samples and associated data, you consent to them being used in cancer research.

2.1 What research will my samples and/or data be used for?

A research project leader (principal investigator) may request samples and associated data using defined project criteria. Your samples and associated data will be made available to research teams who are Research Ethics and GDPR compliant. Your samples and associated data may be used in multiple research projects.

Researchers study biomarkers such as genes (DNA), proteins and RNA to see if they are present in cancer patient samples compared to healthy participant samples. Matching biomarker expression with clinical data identifies biomarker targets for early diagnosis and predicting response to treatment. This helps researchers understand why some people develop cancer while others do not. Some research projects require more than one sample from a participant. By studying samples from different timepoints researchers can observe the effects of different treatments on biomarkers.

Researchers are not permitted to reveal or transfer samples or data to anyone else or to use them for purposes other than those agreed to. If new areas of research and technology, of value to cancer research, arise in the future, the Cancer Biobank will try to provide samples and associated data for this research according to the permissions granted to us by your consent.

2.2 Will I be told the outcome of the research?

No. We do not advise participants of the outcome of research projects based on their samples and associated data. Research findings are published (without compromising participant confidentiality) in the scientific literature.

3. Data Protection

Personal data relating to your participation in the Cancer Biobank will be processed under the University of Galway/Saolta Cancer MCAN Joint Data Controller Agreement. The Joint Controllers have conducted a Data Protection Impact Assessment DPIA202300027. This is a living document which is routinely updated.

3.1 What personal data will be used and will my medical records be accessed?

By participating, you give the Cancer Biobank consent to collect and store identifiable information provided by your clinical team or your medical records, e.g. name, date of birth, address, board number, hospital number, consultant, procedure and specimen related details, family history, medical history, and lifestyle data.

3.2 What will happen to my personal data and who can access it?

Your data will be collected and stored in the Cancer Biobank and Pathology databases and used only for cancer research. Only data that is needed for the cancer research project will be processed.

As a participant you will be given a unique identifier to pseudonymise your identity in the Cancer Biobank. Your data will not be completely anonymised as it is important to maintain a link between your samples and associated data. See Section 1.6. for details on how your data will be stored.

Your identifiable data will be stored indefinitely by the Cancer Biobank. Your pseudonymised data will be stored by relevant researchers for the duration of the research project and will be completely anonymised and/or destroyed upon project completion. The Principal Investigator is the Data Controller for the research project using pseudonymised data. Your pseudonymised data may be analysed at the University of Galway or may be transferred to another research laboratory or statistician for additional analysis. If your data is transferred to researchers outside of the EU, appropriate GDPR compliant safeguards will be ensured, as per Article 45 of the EU Regulation 2016/679.

3.3 How can I be assured my data will be protected?

Your privacy is very important to us. We take many steps to make sure that we protect your confidentiality and keep your data safe. Here are some examples of how we do this:

- The Cancer Biobank database is located on a secure Saolta server. Access to this server is restricted to Cancer Biobank personnel with approved user credentials. All data files containing your data are encrypted using password protection. Pseudonymisation ensures that your identity remains confidential.

- A joint Saolta/University of Galway Data Protection Impact Assessment (DPIA) was performed on data processing for the Cancer Biobank. A low level of risk was identified.
- The Cancer Biobank Data Controllers (Saolta Cancer MCAN and University of Galway) are bound by a professional code of secrecy in relation to your personal data. The Data Processors (University of Galway Cancer Biobank personnel),are bound by a Data Processing and Confidentiality agreement. Research teams are bound by a Cancer Biobank Data Protection Policy agreement. All authorised Cancer Biobank staff and research teams are trained in data protection law and data security.

3.4 Information on Data Protection Laws

What is the lawful basis to use my personal data?

We use your information (the data subject) for biobanking and cancer research. The legal basis is that processing is necessary for the purposes of scientific research that is in the public interest in the area of public health Articles 6(1)(e) and 9(2)(j) of GDPR. For more information, please see: GDPR Directive 95/46/EC.

What are my rights?

GDPR ensures that the rights of the individual are protected. For further details regarding your rights as a data subject, please visit the Cancer Biobank Personal Data Privacy Statement on our website www.universityofgalway.ie/biobank/. You may exercise these rights by contacting the Cancer Biobank, the Data Protection Officer, or the Data Protection Commission (see Section 5).

The Cancer Biobank and research projects are financially supported by the National Breast Cancer Research Institute, University of Galway, national and international funding agencies.

The collection of samples and associated data for the Cancer Biobank has been approved by the Galway University Hospital's Clinical Research Ethics Committee (protocol number 45105 and CA151).

5. Further Information

5.1 Data Protection enquiries contact:

Saolta Cancer MCAN Data Controller:
Saolta Cancer MCAN Director, University Hospital Galway

University of Galway Data Controller:
adminbiobank@universityofgalway.ie

Saolta Data Protection Officer:
Merlin Park University Hospital, Galway
ddpo.west@hse.ie, +353 (091) 775373

University of Galway Data Protection Officer:
dataprotection@universityofgalway.ie

Under GDPR, if you are not satisfied with how your data is being processed, you have the right to lodge a complaint with the Office of the Data Protection Commission: www.dataprotection.ie

Data Protection Commissioner, Ireland:
Canal House, Station Road, Portarlington, Co. Laois.
info@dataprotection.ie; +353 (0761) 104800;
LoCall 1890 252231

5.2 Cancer Biobank or Research information contact:

Cancer Biobank Governance/Director:
Discipline of Surgery, University of Galway
adminbiobank@universityofgalway.ie

Cancer Biobank Laboratory:
adminbiobank@universityofgalway.ie,
+353 (091) 544202
www.universityofgalway.ie/biobank/

5.3 Will I be contacted again?

We request your permission to contact you about further Cancer Biobank activities such as new research, focus groups or questionnaires. You can agree to be re-contacted (or not) on the informed consent form.

If you would like to take participate in the Cancer Biobank, please complete the informed consent form.

Thank you for considering to participate in the Cancer Biobank.