

assists us in diagnosis and prediction of response to therapy. It also gives us a better understanding as to why some people develop cancer while others do not.

- These studies use technology such as cell culture, immunohistochemistry, PCR and genotyping. Some research requires more than one sample from an individual. By studying samples from different time points, researchers can observe the effects of different therapies on biomarkers.
- Researchers are not permitted to give samples or personal information to anyone else or use your samples/information for purposes other than those agreed to. The Principal Investigator is the Data Controller for the research study using your coded information.
- If completely new areas of research and technology arise in the future and are considered valuable for cancer research, the Cancer Biobank will try to provide samples and/or information for this research according to the permissions granted to us by your consent.

Will I be told the outcome of the research?

No, we do not return research results to participants. Research findings are published (without compromising participant confidentiality) in the scientific literature.

Data Protection

Personal information will be processed under the University of Galway/HSE West and North West Cancer MCAN Joint Data Controller Agreement. A Data Protection Impact Assessment (DPIA20230027) has been conducted. This is a living document that is routinely updated.

How can I be assured my information will be protected?

Your privacy is important to us. We take many steps to make sure we protect your confidentiality and keep your information safe.

Here are some examples of how we do this:

- The Cancer Biobank database is located on a secure hospital server. All data files containing your information are password protected.
- De-identification or coding ensures that your identity remains confidential.
- Cancer Biobank personnel are bound by a Joint Controller Data Sharing Agreement with HSE West and North West. Research teams are bound by a Cancer Biobank Data Protection Policy Agreement.
- All Cancer Biobank staff and research teams are trained in information protection law and security.

What is the lawful basis to use my personal information?

All samples and personal information are used for biobanking and cancer research. The legal basis under the General Data Protection Regulation (GDPR) for processing your personal information is in the public interest Article 6(1) (e) and for scientific research under Article 9(2) (j). 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 Privacy Notice on our website, <http://www.universityofgalway.ie/biobank/>.

You may exercise these rights by contacting the Cancer Biobank, the Data Protection Officer (contact info below), or the Data Protection Commission, info@dataprotection.ie.

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 contacted or not on the consent form.

Enquiries

Cancer Biobank

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adminbiobank@universityofgalway.ie

www.universityofgalway.ie/biobank/

HSE West and North West Data Protection Officer:

Merlin Park University Hospital, Galway, H91 N973

ddpo.west@hse.ie

University of Galway Data Protection Officer:

Quadrangle, University of Galway, Galway

dataprotection@universityofgalway.ie

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NATIONAL BREAST CANCER RESEARCH INSTITUTE



As part of our commitment to quality, the Cancer Biobank participates in external quality assessment to verify the precision and efficiency of our biobanking methods.

If you would like to take part in the Cancer Biobank, please sign the Consent Form. You will be given a copy of this information leaflet and a copy of the signed consent form to keep.

Thank you for your interest in taking part in the Cancer Biobank!

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Cancer Biobank

Participant Information Leaflet

The University of Galway in partnership with HSE West and North West would like to invite you to contribute to the Cancer Biobank. The Cancer Biobank is a research resource of human biological samples and associated personal and health related information for use in cancer research studies.

This leaflet is to help you decide whether to donate your samples to the Cancer Biobank for use in future cancer research. Read it carefully and ask as many questions as you like.

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!



<https://www.universityofgalway.ie/biobank/>

Cancer Biobank

What is the Cancer Biobank?

- A cancer biobank is a collection of biological samples and healthcare information donated by people for use in cancer research.
- These donations help researchers better understand health and disease in the human body and find new and improved ways to diagnose and treat cancers.
- Large numbers of samples and information are needed to carry out this research.

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

We invite all patients undergoing cancer investigation and/or treatment to participate. We also invite volunteers from the community setting to contribute to the Cancer Biobank as non-cancer comparisons. **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 impacted in any way.**

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 visits or at arranged sample recruitment drives.
- Only authorised hospital personnel will ask you to participate in the Cancer Biobank. Our staff will explain how you can take part in the Cancer Biobank and will answer any questions you may have.
- If you wish to participate, we will ask you to carefully read and sign the informed consent form.

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

The collection of samples and information for the Cancer Biobank has been approved by the Galway University Hospitals Clinical Research Ethics Committee (protocol numbers 45105 and CA151).

By participating, you give the Cancer Biobank your

consent to collect some, or all, of the following:

- **Tissue:** At the time of biopsy or surgery, we will ask you to donate a small piece of your tissue. This process will not interfere with your diagnosis or treatment.
- **Blood:** We will ask you to donate 4 tubes of blood, each about 5 mL in volume (1 teaspoon). These are in addition to the bloods taken for your clinical diagnosis or treatment.
- **Fixed Tissue Blocks:** We are asking your permission to access excess tissue in fixed tissue blocks, which are routinely prepared from tissue taken during biopsy or resection. After diagnosis, these blocks are routinely stored in hospital Pathology departments for future diagnostic and medico-legal purposes.
- **Other:** Occasionally other types of samples may be requested. These might include saliva 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 visits.
- **Personal Information:** In addition to your samples, we are asking permission to access information that is relevant to your diagnosis, treatment, and follow-up visits. 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, medical history, and lifestyle information.

How are my samples and information stored and what are they used for?

The Cancer Biobank is a long-term research resource. This means that your samples and information will be stored until they are required for use in cancer research studies.

Samples: Biological samples are stored in ultra-low freezers (-70 °C). Your samples will be given a unique identification number or code. Researchers using your samples will not be able to identify you personally.

Personal Information: Your identifiable information will be stored on hospital servers in the Cancer Biobank and Pathology Databases that are accessible by authorised

personnel only. Only information that is necessary to achieve the objective of the cancer research study will be collected. Your information will not be made completely anonymous, as it is important to maintain a link between your samples and information.

- Your identifiable information will be stored forever by the Cancer Biobank. Your de-identified or coded information will be stored by researchers for the duration of the research study. Upon completion of the study, remaining samples will be returned to the Cancer Biobank, or they will be destroyed.
- Your coded information may be analysed at the University of Galway or may be transferred to another research group for additional analysis. If your information is transferred to groups outside of the EU, appropriate GDPR compliant safeguards will be ensured, as per Article 45 of the EU Regulation 2016/679.

What are the benefits to participating in the Cancer Biobank?

- You will not directly benefit from taking part in the Cancer Biobank. Your samples and/or information will contribute to research that could benefit patients in the future.
- Your samples and information will not be used for commercial gain. If knowledge gained from such research leads to a commercial development, you will not benefit financially.

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

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

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, you have following options:

- **No further access:** This means that the Cancer Biobank will not access your medical records any further but would still have your permission to use the samples and information you have already provided.
- **No further use:** This means that your samples and information stored in the Cancer Biobank could no longer be used for research and would be destroyed. All remaining fixed tissue blocks would be retained in hospital Pathology departments. Your signed consent and withdrawal forms would be kept as a record of your wishes.
- **No further contact:** This means our research team can no longer reach out to you, but the continued use of your previously obtained samples and information is permitted. Obtaining further information from your relevant medical records is also permitted.

To withdraw from the Cancer Biobank, please contact us by post or email to obtain a participant withdrawal form. See Cancer Biobank contact details at the end of this leaflet.

Research

By giving your explicit consent to store your samples and information in the Cancer Biobank, you consent to them being used in cancer research.

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

A research project leader or Principal Investigator may request coded samples and information for a clearly defined study. Your samples and/or information will be made available to research teams who have been granted ethical approval for their study. Your samples and/or information may be used in multiple research studies.

- Researchers study biological molecules (biomarkers) such as genes (DNA) and proteins to see whether they are present at different levels in diseased compared to healthy participants' samples. The relationship between a particular molecule and clinical information