Cancer Biobank - Participant Information Leaflet

NUI Galway in partnership with Saolta University Health Care Group (Saolta) would like to invite you to contribute to the Cancer, Managed Clinical and Academic Network (MCAN) Biobank (henceforth referred to as the Cancer Biobank). The Cancer Biobank is a research resource of human biological samples and associated personal and health related data for use in molecular and cellular cancer research studies.

This information leaflet will help you decide whether you want to participate or not.

1. Cancer Biobank

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

Cancer is a complex disease, affecting individuals differently in how their cancer develops and responds to treatment. The development of more effective intervention against cancer requires a better understanding of its molecular basis and translation of laboratory findings into improved patient care. The Cancer Biobank enables translational research by using patient samples and laboratory models to study cancer. Large numbers of samples and data are needed to carry out translational research.

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

We invite all patients who are undergoing cancer investigation and/or treatment in clinics to participate. We also invite volunteers from the community setting to join the Cancer Biobank 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 sample recruitment drives.

Only authorised Saolta personnel will ask you to participate in the Cancer Biobank. Staff will explain how you can take part 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, 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 that you donate a small piece of your tissue. This process should not in any way interfere with your diagnosis or treatment.

Blood: We will ask you to donate 4 tubes of blood, each containing about 5 mL (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. This tissue is also useful for cancer research. 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 reseach 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 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 Biobanked and what they are used for?

Your samples and data will be collected and stored as part of the Cancer Biobank, which is located at the Lambe Institute, NUI Galway.

Your **sample** details will be entered into the Cancer Biobank database by biobank personnel and into the Pathology database by authorised personnel. The data relating to your samples is 'pseudonymised' which means that each participant is given a unique identification number. Researchers using your samples and data will not be able to identify you personally. Samples are stored in ultra-low freezers (-70^{o}C) using codes generated by our secure software system.

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

The Biobank is a long-term research resource. Your samples and/or 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 Clinical Research Ethical approval for their studies. Research may take place in the Lambe Institute or also in other collaborating research institutions.

1.7 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 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/or data will not be used for commercial gain. If knowledge gained from such 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 is no additional risk 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, we ask that you 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 would still have your permission to use the samples you already provided.

No further use: This means that any of your donated samples 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 form would be kept as a record of your wishes.

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

2. Research

By giving your explicit consent to biobank your samples and 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 data using clearly defined study criteria. Your samples and/or data will be made available to research teams who have been granted research programme and ethical approval and are GDPR compliant. Your samples and/or data may be used in multiple research studies.

Researchers study biomarkers such as genes (DNA), proteins, and RNAs to see whether they are present or expressed at different levels in diseased compared to healthy participant's samples. The correlation of gene, protein or RNA expression with clinical data, identifies molecular profiles for early diagnosis, more accurate prediction of response to

therapy and provides us new knowledge as to why some people develop cancer while others do not. These studies use technology such as PCR, cell culture, flow cytometry, western blotting, electron microscopy, cell interaction assays, immunohistochemistry, and genotyping. Some research requires more than one specimen 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 reveal or transfer samples or data to anyone else or to use them for purposes other than those agreed to. If completely new areas of research and technology arise in the future and are considered valuable for cancer research, the biobank will try to provide specimens and/or 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 individual results based on their samples and data. Research findings are published (without compromising participant confidentiality) in the scientific literature.

3. Data Protection

Your Cancer Biobank-related personal data will be processed under a NUI Galway (*Data Processor*)/Saolta Cancer MCAN (*Data Controller*) Data Processing and Confidentiality Agreement.

3.1 What personal data will be used? 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, 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 the Pathology database and used solely for cancer research. Only data that is necessary to achieve the objective of 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 data.

See Section 1.6. for details on how your data will be stored. Your identifiable data will be stored indefinitely by the Biobank. Your pseudonymised data will be stored by relevant researchers for the duration of the research study and will be completely anonymised and/or destroyed upon study completion. The Principal Investigator is the Data Controller for the research study using pseudonymised data.

Your pseudonymised data may be analysed at NUI Galway or may be transferred to another research laboratory or statistician for additional analysis. If your data 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.

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

Your privacy is 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 database server. Access to this server is restricted to Cancer Biobank personnel via user account credentials. All data files containing your data are encrypted using password protection. Pseudonymisation ensures that your identity remains confidential.
- A joint Saolta/NUI Galway Data Protection Office Data Protection Impact Assessment (DPIA) was performed on the Cancer Biobank-related data processing. A low level of risk was identified.
- Saolta Cancer MCAN as data controller is bound by a professional code of secrecy in relation to your personal data. Cancer Biobank personnel, as NUI Galway data processors are bound by 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 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 the area of public health pursuant to Article 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 http://www.nuigalway.ie/biobank/.

You may exercise these rights by contacting the Cancer MCAN Biobank, the Data Protection Officer, or the Data Protection Commission (see Section 5).

4. Financial Support and Ethical Approval

The Cancer Biobank and laboratory studies are financially supported by the National Breast Cancer Research Institute, NUI Galway, Galway University Foundation, national and international funding agencies.

The collection of samples and data for the Cancer Biobank has been approved by the Galway University Hospitals 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 adminbiobank@nuigalway.ie
Saolta Data Protection Officer	Merlin Park University Hospital, Galway ddpo.west@hse.ie, +353 (091) 775373

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, NUI Galway adminbiobank@nuigalway.ie
Cancer Biobank Laboratory	adminbiobank@nuigalway.ie, +353 (091) 544202 www.nuigalway.ie/surgery

5.3 Will I be contacted again?

We would like to contact you to request your involvement in 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 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 considering to participate in the Cancer Biobank