

1. Why have I been given this information sheet?

We have given you this information sheet as we are inviting you to take part in our 'biobank' because you have been or are being assessed for a possible blood disorder.

This information sheet tells you about the biobank and what will be involved if you decide to take part. Please read it carefully and think about taking part in the study. Your hematology doctor and nurse will be happy to answer any questions that you may have.

2. What is a biobank?

Before a new drug is used in hospitals, it is tested thoroughly to make sure it works and is safe to use. Part of this testing involves studying tissue samples donated by patients.

A collection of tissue samples donated by patients is called a biobank.



3. What is Blood Cancer Biobank Ireland?

Blood Cancer Biobank Ireland is a biobank that collects tissue samples donated by patients who may have a blood disorder. At present, we are collecting samples from patients in Galway, Cork and Dublin, and in the future, we will collect samples from patients all over Ireland.

4. Why is this study being done?

We are doing this study bring new and better treatments to blood cancer patients in Ireland.

5. What is involved in the study?

Our biobank collects two types of tissues: bone marrow and blood. Researchers study these samples to understand how blood cancers develop and how we can design better treatments for blood cancer patients.

We also work with the National Cancer Registry Ireland to collect clinical information (such as the type of the blood disorder, the treatment and the patient's response to it). Researchers use this information to better understand diseases.

Our study will also collect information you give us voluntarily (if you decide to take part), on how effective you found the treatment, your quality of health and your overall wellbeing. This will help researchers and doctors to decide on the best therapy to be used in the future.

6. What will happen if I decide to take part?

We will ask you to sign an Informed Consent Form. Your hematology doctor will then collect about 2 tablespoons (20 ml) of your bone marrow and blood.

We will store these samples in the biobank and use them for current and future research.

The National Cancer Registry Ireland (NCRI) may also send you up to three short questionnaires about your quality of health and how you feel after your treatments. We would ask you to fill in these short questionnaires and send them back to the NCRI. If you need help to fill out the questionnaires, just ask your nurse at a time that suits you both.

7. Are there any risks to me from taking part in the study?

There are no particular risks from taking part in our biobank. The haematology doctor will collect samples for the biobank at the same time as they collect your routine clinical samples. Some people may experience bruising or discomfort at the site where the needle entered, but this will pass in a few days. As always, your doctor and your nurse will do their best to avoid causing you discomfort.

8. Are there any benefits to me from taking part?

There are no direct benefits for taking part in this biobank. Your samples, along with many others, will be included in research studies that will help future cancer patients. You will not get any money or compensation for taking part in the biobank.

9. How many people will take part in the study?

This study will collect blood and bone marrow samples over many years. We aim to collect 300 samples in the next five years which will greatly help researchers to

understand more about blood cancers and find better ways to treat them.

10. What will happen if I decide not to take part?

It is entirely up to you whether you take part or not. If you decide not to take part, it will not affect your treatment or care in any way.

11. What happens if I change my mind?

You can change your mind at any time by contacting us. We will destroy all samples and clinical information about your samples that we hold. When we do this, it will end all means of linking you to the project. Be assured that you won't be identifiable from the samples.

If a long time has passed by the time you change your mind, your samples may have already been used for research studies and it may not be possible to get them back.



12. How long will I be involved in the study?

You will be involved in the study only while you are attending your regular procedures. When your doctor collects the samples of blood and bone marrow needed for your care, they will also take the samples for the biobank. You don't have to come in for any extra procedures. The biobank will store your donated samples and the relevant clinical information on your disease for several years so researchers can use them in many research studies.

13. Is taking part in the biobank confidential?

Yes. Only your hematology doctors and nurses will access your medical records and personal information.

The hospital where you receive your treatment is responsible for keeping your medical details and personal information safe and secure in line with the law on data protection. Your personal information and full medical history will only be stored in the hospital's official medical records. The biobank will only collect the clinical information relevant to your disease.

To fully protect your privacy, the hospital will put an **anonymous code** on your donated tissue samples. The biobank stores your donated samples and the relevant clinical information only under this code. Researchers will receive tissue samples or clinical information from the Biobank with this code only. They will never receive your name or other information that could identify you.

The hospital will also give the National Cancer Registry Ireland (NCRI) your biobank code. This allows the NCRI to identify you on their database and give the biobank information that is relevant to your

samples. The NCRI will only pass on information about your blood disorder using this anonymous code. It will not pass on any information that would identify you.

14. Who has access to the biobank?

Our researchers can access the biobank to carry out their research studies. Other research groups and pharmaceutical companies with whom we work can apply to access the biobank for their studies. All these studies must have official approval from the Ethics Committee of the hospital or university where they work to make sure the research is done in an ethical way.

15. Will I learn the results of the research studies?

It is unlikely that the research will discover anything that will directly benefit your current treatment. The studies may investigate genes, especially defects in them that may cause blood cancers, or study new treatments and drugs. 'Genes' are molecules (tiny particles) that carry the instructions about how our cells and body work.

Findings from these research studies and any information on any genes will never be linked to your personal data or identity. If you are interested in research that used biobanked samples, please visit the website of Blood Cancer Network Ireland (www.bloodcancers.ie), where we will put up the scientific discoveries that used biobanked samples and data.

16. Who do I contact if I have any questions or concerns?

If you have questions about your treatment, care or tissue samples, it is best to speak first with your doctor, nurse or haematology team.

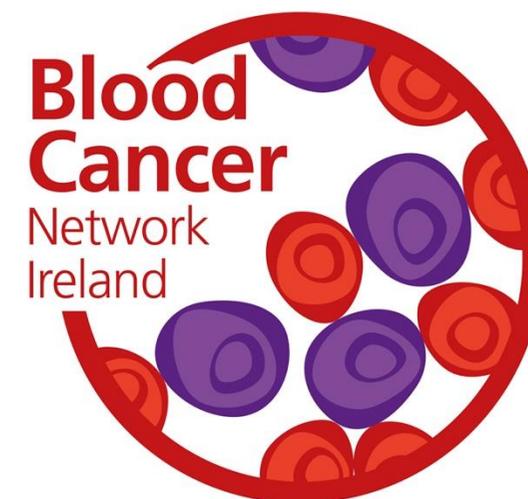
If you have broader questions about the study, you can contact one of the following:

Hematology Department
University College Hospital Galway
Tel.: (091) 544 610

Dr. Eva Szegezdi
Head of Blood Cancer Biobank Ireland (BCBI)
Email: eva.szegezdi@nuigalway.ie

If you have any worries about this study and want to speak in confidence with someone who is independent, you can contact the Research Ethics Committee of the National University of Ireland Galway:

Tel.: (091) 775 022
E-mail: ethics@nuigalway.ie.



PARTICIPATING IN BLOOD CANCER BIOBANK IRELAND

INFORMATION LEAFLET FOR PATIENTS