

**STANDARD**

**Patient Information Leaflet**

**and Consent Form**

**1. Invitation**

We are inviting you to take part in our biobank.

**Taking part is your own decision and you are fully entitled to refuse to give your sample.**

Your decision will not affect your care in any way. Before you decide, it is important for you to understand what a biobank is and what is involved. Please ask us if there is anything that you find unclear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this.

**2. What is a biobank?** A biobank collects and stores, for use in future studies:

• tissue;

• **biological samples** – blood, urine, serum and saliva; and

• health information (data).

Our biobank aims to provide samples and health-related information (data) to researchers to help increase our understanding of cancer, and develop new tests and treatments. This is an ongoing study that will collect tissue, **biological samples** and data over many years.

**3. What will it involve, if I decide to take part?**

If you agree to take part, we will ask you to sign the Consent Form. We will give you a signed copy of the Consent Form and this Patient Information Leaflet to keep. Here is what will happen next.

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**3.1 Your sample**

A pathologist or trained personnel will examine your operation sample in the lab. If there is extra tissue available, then we consider your operation sample suitable for our biobank. Occasionally, this may happen before you are able to read this leaflet. However if you do not consent nothing further will be done and your operation sample will not be sampled for the biobank.

**3.2 Other samples**

We may also ask you to give a sample of one or all of the following:

• blood • urine • serum • saliva.

If your sample is suitable, we will store it and your health-related information (data) in the biobank. We will keep your samples and data as long as they are useful; this may be for a long number of years.

**3.3 Research use**

We will let researchers use the materials stored in our biobank for approved studies. Researchers who can apply to use your samples and health-related information (data) may come from:

• hospitals;

• third-level institutions (colleges and universities); and

• biopharmaceutical companies (companies that make drugs).

Our scientific committee will review each request. Each project must have ethical approval before applying to us to use samples. That means they must have a proper moral reason for applying.

In order to help sustain the biobank infrastructure a small administrative fee (not for profit) will be charged to the research applicants to help with these costs.

**3.4 How we store and share your health-related information (also called data)**

If you agree to let us use your samples, we will store your health-related information on databases

at the hospital (Biobank Information Management System) where you receive treatment and we may share it with authorised researchers.

We will store your information in two ways:

• **coded data**: anything that could identify you, such as your name, address or date of birth is removed. Therefore researchers cannot link you to your samples.

• **non-coded data**: researchers will know which samples belong to you, because we will link your name, hospital number and histology/laboratory number to your samples.

Only authorised researchers may be able to access coded and encrypted data through a password protected web portal. **Hospital approved staff**, at the hospital where you receive treatment, may

read your hospital charts while doing their work on your samples. **Hospital-approved staff**, are

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approved researchers who work directly for clinicians, at your hospital. In large studies your information may be used to design studies and understand experimental results, but this will only happen as outlined in point 9.

**3.5 Other research projects**

Your samples may be included in many research projects. An Ethics Committee must approve each project before we give samples to these projects.

**4. What happens if I decide not to take part?**

Nothing. We will examine your operation sample in the usual way **but** without sampling for the biobank. It is up to you to decide whether or not to take part. If you decide to take part, you will be given this Patient Information Leaflet to keep and asked to sign a Consent Form. If you decide to take part you are still free to withdraw at any time in the future, without giving a reason. This will not affect the standard of care you receive.

**5. What happens if I change my mind?**

You can change your mind at any time by contacting us. Our contact details are given in point 12. We will send you a form, and when you complete this form and return it to us, all samples and information still in our possession will be destroyed. If you change your mind after a long time, some samples may have already been given to researchers. It is not possible for us to get samples or information back from researchers once they have them. When we destroy your samples and data,

it will destroy all means of linking you to any samples that have already have been given to researchers.

**6. What kind of research will my samples be used for?**

Your samples may be included in studies that investigate different aspects of cancer. Future research may include research which looks to understand genetic influences related to:

• cancer growth;

• early detection; and

• treatment.

Your samples may also be used to develop new cancer-related tests and treatments. We cannot give exact details about the projects which may include your samples, because the ideas for these projects have yet to be thought of. However, your samples will only be included in projects which are ethical, that is, they have been approved by an ethics committee.

**7. What are the risks associated with taking part in the biobank?**

No major physical risks are associated with donating tissue to the biobank. When you give us permission to biobank, we take surplus tissue from an operation sample that **would otherwise be**

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**destroyed** (after diagnosis). If you give blood samples, you may have some bruising and minor discomfort. We don’t expect any other risks associated with donating blood, urine, saliva or serum. There is a slight risk that someone could discover who you are through one of the databases. We are taking several precautions to protect your privacy (see point 9).

**8. How is my privacy protected?**

We give each sample a code which makes it difficult to identify who you are. Clinicians at the hospital, you are attending, may wish to include your samples in their research. **Hospital-approved staff**; are approved researchers who work directly for these clinicians, at your hospital. They may read your hospital charts, while doing their work on your samples.

The hospital where you receive treatment is responsible for keeping your data safe and secure.

We also provide the National Cancer Registry (NCR) with information that includes your code, name, address and date of birth. This allows the NCR to identify you on their database. If the NCR wish to pass on your data (age, weight, medical history) to researchers, they do not pass on any information that would identify you. **If we give your information to researchers, outside your hospital, we include only the code and leave out anything that would identify you**.

**9. What are the benefits associated with taking part in the biobank?**

It is very unlikely that you will directly benefit from the research, because we spend years doing the research and then using important findings for new cancer tests and treatments. But an organised biobank will speed up this process. We hope that your samples, along with many others, will be included in research that will help future cancer patients. You will not get any money should research lead to a new test or treatment.

**10. Will I be told about the research results?**

Most research is unlikely to discover anything that is specifically relevant to you. We will put reputable scientific papers, from the research done using your tissue and the tissue of other patients, on our webpage

**For more information contact the Biobank:**

**Contact:** Jane Doe. Phone 01 - 234 5678

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