

Northern Ireland Biobank Information Sheet

We are inviting you to donate samples to the Northern Ireland Biobank (NIB). Before you decide whether or not to participate, please take time to read this information leaflet. Ask us if there is something you do not understand, or if you would like more information.

What is the Northern Ireland Biobank?

The Northern Ireland Biobank is a joint project between The Northern Ireland Health and Social Care Trusts and Queen's University Belfast (QUB). It was set up to create a resource of biological samples such as blood and tissue which can be used in research studies to find new ways of diagnosing and treating disease.

Why have I been asked to do this?

We are asking you to consider donating samples because you are currently receiving medical treatment or care which may involve a surgical or medical procedure and/or a blood test.

Do I have to take part?

No. You do not have to consent – the choice is yours. If you decide not to take part, it will NOT affect your care in any way and your tissues will be used solely for your care alone.

What will happen if I say yes?

Surplus samples

If you are having a surgical procedure or blood test, the tissue and/or blood that is removed is sent to the hospital laboratory for analysis to help your doctor make decisions about your care. The priority of the Health Trust will be your diagnosis; however, not all of the material removed may be needed for this. In the normal course of events, any surplus or leftover material is discarded. We are asking your consent to bank some of this leftover material so that it may be used for future research projects

Samples collected specifically for NIB

We also ask your permission to collect a small amount of additional blood from you. This is usually done at the time of your procedure and can be up to 40mls which is approximately 8 teaspoons. In certain cases, where relevant, we would also like your consent to take an additional sample of bodily fluid such as urine, saliva or ascites. These will be stored together with your blood and tissue.

Tissue from previous surgeries

If you have had a previous surgery, some of your tissue will be stored in the hospital pathology laboratory. This tissue can also be used for research and we would like your permission to transfer these to the NIB and make them available for approved research studies.

Repeated donation

Sometimes we may ask your permission to collect several samples over a period of time, to compare samples from before, during and after treatment. All repeated donations will be arranged to coincide with your routine appointments to ensure no inconvenience to you.

What will happen to my samples?

Your samples will be labelled with a unique NIB number and transferred to our secure storage facility in QUB. Most samples are stored here until they are ready to be released to an ethically approved research study.

Cell Culture Models

On occasions, a sample may be released immediately after it has been received by NIB to allow cells to be put into culture. Some scientists wish to study how diseased cells grow and are maintained in the body. They can use laboratory techniques to study how individual cells respond to new drugs and treatments. The cells may be grown on special plastic dishes or in three dimensional gels in the laboratory environment; or they may be stored in a freezer for a period of time and studied at a later date. Some cells may need to be treated with laboratory reagents to make them grow indefinitely in culture so that scientists can study how they grow over longer periods of time.

Genetic Analysis

Some samples may have their DNA extracted. DNA is used to make genes that control development, growth, eye colour and many other things. When certain genes and proteins in the body become abnormal, they can cause normal cells to become diseased. It is an important part of research to understand what genes and proteins do within cells. We may therefore use part of your sample to obtain DNA (genetic material) and make it available to research groups to try to find out what gene patterns may increase the risk of different types of disease or to see whether we can predict what treatment may be best.

What are the risks and benefits of taking part?

Samples will be mostly be taken as part of your routine procedure or care so there should be minimal risk associated with taking part in this project.

You may not directly benefit from your donation. Rather, your participation will add to medical knowledge for future generations and may help in the discovery of new treatments for serious illnesses and conditions.

What about my personal information?

We need to collect and hold your personal information (name, address, Health and Care number, date of birth) to make sure we are matching the correct medical record to the correct donated samples. This is stored securely in our QUB electronic tissue bank database. Within this database we also hold an electronic copy of your consent form. We will also collect and hold personal information about your diagnosis and treatment such as specimen type, pathology and date of operation. Researchers may apply through a formal process to get access to information

linked to your samples to better understand the risk of certain diseases and how develop new treatments. However, when information is released to a researcher, it is linked only to your unique NIB code number. We will never give researchers your personal identifiable information such as date of birth, address or Health and Care number.

We take your privacy seriously. In order to protect your privacy we will:

- Remove personal identifiers such as name or date of birth from your samples and information and assign a unique NIB code number instead. Samples and data released by NIB will not be traceable to you as they are labelled only with this unique code.
- Keep the paper copy of your consent form in a secure, restricted access location within Queen's University Belfast.
- Use security measures such as data encryption and access controls to ensure only authorized individuals have access to your personal information stored on our electronic database.

As consent to 'gifting' your samples will be enduring, we will continue to hold your samples and information unless you advise us you wish to withdraw consent.

What happens if I change my mind?

You can withdraw your consent at any time by phoning or writing to the NIB Administrator whose contact details are given at the end of this information sheet. We cannot always guarantee that all of your samples will still be available as they may already have been released to researchers. If you change your mind, any remaining tissue/blood samples, gifted to the NIB, will be destroyed your information will be removed from our database. Withdrawing consent from the NIB will NOT affect your treatment or care in any way.

Who can access my samples?

Only approved research studies can get access to your samples. Researchers must demonstrate that their studies are ethical and of high quality. Independent experts will give their specialist opinion on the proposed research before access to tissues is approved.

Samples may be released to academic institutions, the NHS or commercial companies. Future approved research using your samples may result in financial gain to commercial organisations which are developing new tests and treatments. However, no direct financial benefit will accrue to NIB or to you as a donor. NIB approved projects could also involve portions of your samples and coded data being exported to research laboratories in other countries world-wide.

Return of research results

Researchers are unable to trace your samples back to you therefore you will not receive any personal feedback. Details of research studies that have used NIB samples are available on our website.

Who funds the NIB?

The Health and Social Care Research and Development Division of the Public Health Agency (HSC R&D Division) has provided the majority of the funding for the biobank.

Who ensures the integrity of the Biobank?

NIB has been ethically approved by a local research ethics committee and must conform to national rules to ensure that patients are protected. Tissue is stored under a licence from the Human Tissue Authority. A committee structure is in place to ensure the Biobank complies with these rules and regulations.

What if I have a complaint?

If you have a complaint, in the first instance you can contact the NIB Administrator (details below). If your complaint has not been handled to your satisfaction or you would rather discuss it with someone outside the NIB team, you can contact the Head of QUB Research Governance, Ethics and Integrity:

Email: researchgovernance@qub.ac.uk
Tel: 028 90972572

Contact for further information

Write to: Northern Ireland Biobank
Patrick G Johnston Centre for Cancer Research
Queens University Belfast
Belfast
BT9 7AE

Tel: 028 90972915
Website: www.nibiobank.org
Email: nibiobank@qub.ac.uk