

# Organ Donation and Tissue Donation for Research

**Thank you for your generosity in supporting our research. This vital work has the potential to benefit many patients, both now and in the future.**

We know from experience that the information you have been given can be difficult to remember, and as such, have designed this leaflet to help answer any questions you may have.

## **What is research?**

Studying human organs and tissues is essential to gain a better understanding of the structure, function and disorders of the human body and for developing new treatments for diseases.

Research allows doctors and scientists to look at how different parts of the body work and importantly, learning from research may result in new medicines or new practises that save lives and help more people recover from illness and disease.

## **What does research involve?**

Samples removed for research can range from an additional blood sample or a small piece of tissue to look at cells under a microscope, to removing whole organs to assess their function.

Donated organs, tissue and additional samples e.g. blood and urine are used to support ethics approved studies to better understand how diseases can be prevented, cured or improved with new treatments.



Most samples that are donated support transplant-related research programmes whilst other samples may be placed into a secure research tissue bank and made available to approved researchers and projects in the future.

In some cases, testing involving animals may be required. Research within the UK that uses animals is very tightly regulated by the Government. Research studies involving animals only happen when there is no alternative way to find out the answer to a scientific question, to understand a disease, or develop a new treatment.

Sometimes genetic (DNA/RNA) analysis may be carried out. Researchers may look at the chromosomes, genes, or proteins that are found in cells and the results of these studies can help understand disease processes e.g. cancer and future treatments. For example, some proteins may change in type or increase in quantity in certain diseases. Knowing about these changes may provide information about how well an organ will function when transplanted.

In addition to research you will have been informed or asked about donating organs and/or tissue for the following purposes:

**Education or Training** specifically refers to medical or healthcare education and training e.g. training in new surgical techniques.

**Audit** aims to improve the quality of patient care or a service by looking at current practice and changing it where necessary.



**Quality assurance** which is carried out to monitor and evaluate such things as the techniques used to process a donated tissue product, or otherwise assess a service or facility to make sure that standards of quality are being met.

In England, Wales and Northern Ireland you will also have been informed or asked about donating organs and/or tissue for the following purpose:

**Performance assessment** evaluates and assesses diagnostic tests. For example, a tissue sample that is known to be normal can be used to check that a medical device is performing correctly.


### **If I give consent/authorisation for research will my relative's organs and/or tissues definitely be used?**

Even if you kindly give consent/authorisation for organs and/or tissue to be used in research, unfortunately sometimes this cannot happen.

The Specialist Nurse will have explained that in some circumstances organ and/or tissue donation for transplantation may not occur at all. If this is the case, then donation of organs and/or tissues for research may also not proceed.

Sometimes we find that there are no suitable approved research studies or research tissue banks who can accept the organs and/or tissue at that time of donation. If that happens these cannot be used and will be respectfully and lawfully disposed of under strict policy conditions.

We are very supportive of research and would always want to honour a family's decision for organs/tissue to be donated for this purpose or one of the other activities outlined above wherever possible.



## How is information about the donor used?

Sometimes the researchers need to know limited information about the person who donated the organs and tissue. This information may have an impact on whether they can use the organ or tissue in their research and the types of studies they carry out, and could include the donor's medical history, whether the donor smoked, their age and gender, and other information you have provided.


Researchers and research tissue banks using donated organs may see identifiable information about your relative in the same way that transplant centres do; such researchers will have received ethics permission to do so. They will anonymise these details upon receipt of the organ whilst safely and securely disposing of the identifiable information.

Researchers and research tissue banks using donated tissues will receive anonymised samples and will not have access to any identifiable information about your relative.

In line with national healthcare research guidance, researchers and research tissue banks must be able to demonstrate that lawful consent/authorisation is in place for research when they receive and store organs and tissue.

To do this they can request a copy of the consent/authorisation for organ and/or tissue donation form from us. If this is the case, your name, signature, your relationship to the person who donated and the time and date that you signed the form will be visible to the researchers along with the donor's information.

All other information about you and your relative (such as your address, contact details and the name and date of birth of your relative) will be redacted and will not be shared with the researchers.



## How is research funded?

The research centre may charge for providing human tissue samples to researchers, including those working for private companies, so that their running costs (transport, security and storage) are recovered and the viability of the bank is maintained. Funding may come from a grant, a university, a hospital or from a commercial company.

The Directorate of Organ and Tissue Donation and Transplantation (OTDT) asks research studies to contribute an administrative fee and annual renewal fee to in part cover the costs associated with supporting research studies. This approach is in line with NHSBT and the wider research sector.

## Where is research carried out?

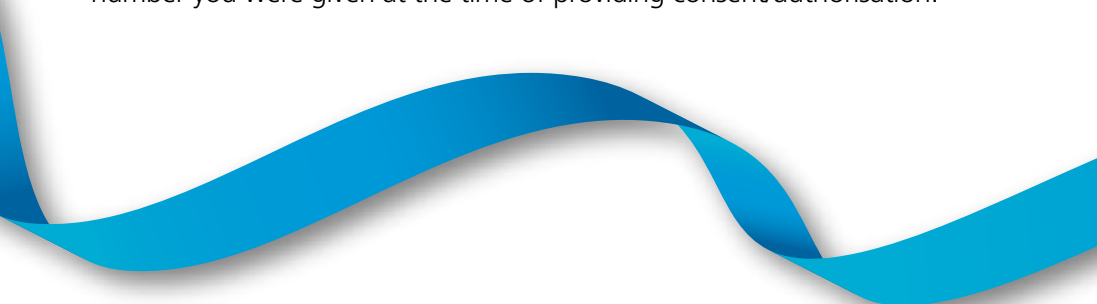
All research will be undertaken in designated research establishments and carried out by researchers who have obtained both legal and ethics approval, following rigorous approval processes to ensure that the donor's gift is used appropriately. The organisations involved in research have mechanisms in place that ensure that all organs/tissues can always be traced to the research studies.

Some research centres co-operate nationally and internationally to ensure that research results can be shared and developed into new treatments. This may mean that tissue or blood samples could be sent to centres in other countries.

## What if I change my mind?

This is an important decision and you are able to change your mind.

It is possible for you to withdraw consent/authorisation for research up to the point at which donated organs or tissue are used. If you want to discuss withdrawing your consent/authorisation for research, please contact the number you were given at the time of providing consent/authorisation.



## What happens after research is complete?

At the end of any research studies, remaining samples will be carefully disposed of or stored in licensed research tissue banks in line with the guidance laid out by the Human Tissue Act (2004) or the Human Tissue (Scotland) Act 2006.

## Further Information

For examples of how organs and tissue donated for research help others and for recipient, patient and family stories, please visit our website at [www.organdonation.nhs.uk](http://www.organdonation.nhs.uk) or [www.nhsbt.nhs.uk](http://www.nhsbt.nhs.uk) or [www.organdonationscotland.org](http://www.organdonationscotland.org)

If you do not have internet access and would like us to send you information, we can arrange this for you.

Thank you for taking the time to read this information and please do not hesitate to ask your nurse if you have any further questions.

For further information please see the privacy statement on NHSBT's website: <https://www.nhsbt.nhs.uk/privacy/>