A University of York service providing human tissue, donated by the patients of York Teaching Hospitals, for research to improve the understanding, diagnosis and treatment of human disease.

Biomedical research needs access to human tissue (such as blood, organ biopsies and tumours) to help develop better treatments for disease. We would like to invite you to donate some tissue to be used for research. Before you decide whether you would like to donate you need to understand why we are collecting the tissue and what it would involve for you. Please take the time to read the following information carefully. One of our team will go through the information sheet with you and answer any questions you have. Talk to others about the facility if you wish.

What is the purpose of the tissue bank?
To understand how our bodies work and how diseases develop, researchers need access to tissue. Looking at this tissue can reveal information that can help develop new diagnostic tests and treatments. Tissue banks, such as ours, aim to collect and store tissue for researchers to use now and in the future.

Why have I been invited to donate to the tissue bank?
We are inviting you to donate tissue because you are having treatment or an operation that will require the removal of some tissue or blood. Your doctors will look at the tissue, as they would normally, and take any that they need for your treatment and care. With your permission, we will collect the remaining tissue, which would normally be discarded, and store it. If you are just giving a blood sample, we may ask if you would be willing to provide an additional sample, solely for the tissue bank.
Do I have to donate my tissue?
No. You are under no obligation to donate a sample of your tissue. Your decision to take part, or not, will not affect your treatment.

What will happen to me if I decide to donate my tissues?
You will receive your care as normal, any operation or blood collection will be done in the same way as patients not donating to the tissue bank. Any tissue required for treatment or diagnosis will be taken by the clinical team. After your doctors have looked at this tissue and taken what they need, some or all of the remaining tissue, will be collected for the tissue bank. The tissue taken for the bank would normally be thrown away. Additional tissue solely for research will never be removed from you at any time without your consent.

We may also ask for an additional blood sample, which you would not normally give as part of your treatment. This sample would be entirely for the tissue bank, but you are free to decide not to give this extra sample if you wish.

What will I have to do?
If you are having an operation you will be given the opportunity to speak to a doctor or nurse. They will answer any questions you may have about donating your tissue and make sure that you fully understand what is involved. If you decide that you would like to donate, you will be asked to give your written consent by signing the tissue bank consent form.

If you are just having a blood test, you will undergo the same process as above at your regular scheduled appointment.

What are the possible risks of taking part?
There are no additional risks to you from donating your tissue to the tissue bank. We collect tissue that is normally collected but is surplus to your diagnosis. You will not have any extra procedures other than those directly relating to your care.
If you give consent to donate an extra blood sample, we will try and collect this at the same time as the blood samples taken for your medical care. If this is not possible the blood will be collected by a trained nurse or doctor, who will take the blood from a vein in your arm using a needle. You are free to change your mind and refuse to give this sample at any time.

**What are the possible benefits of taking part?**
You will receive no direct benefit from donating your tissue. However, results from research using the material from the tissue bank will provide information that may help the development of future treatments and vaccines.

**What will happen if I no longer want my tissues to be used in research?**
You will be free to change your mind about participating and withdraw your tissue from the tissue bank at any time. If you change your mind and wish to withdraw your consent please tell your nurse, doctor or contact the tissue bank (details on page 5) and we will dispose of any samples we have collected in accordance with your wishes.

**What if there is a problem?**
If you have any issues or would like more information, please feel free to contact the tissue bank using the details on page 5.

**Why do you need to access my medical notes and will my information be kept confidential?**
In order to make best use of any material you donate, we need additional information about you. Factors such as age, treatments and gender can all affect the outcomes of analysis of your tissue. We will collect this additional information from your medical notes. All personal information, such as your name and address, is stored at the York Teaching Hospital only. This data is only accessible by the hospital based clinical research team who never sees any research data together with your personal details. Donated tissue that is sent to University of York for laboratory research is anonymised. Laboratory scientists never have access to personal information, and only data relevant to the tissue given will be released to them. All data stored as computer files will be password protected.
What will happen to any samples I give?
If you consent, some or all of the excess tissue, not required by your doctor, will be sent to the University of York where we will store it. We will invite researchers from the UK and abroad to apply for access to the tissue for their research. The University Ethics Committee will look at their applications. They will check that the proposed research idea is achievable and has the potential for healthcare benefits.

The tissue will be available for a wide range of research interests. Genetic (DNA and RNA) analysis may be carried out on the tissue as this is one of the most useful ways of investigating how disease develops. The tissue bank may also work with commercial partners, and these will undergo the same rigorous and independent assessment as academic partners when applying to use the tissue. For more information on how we use the material visit the website, https://www.york.ac.uk/cii/clinicaltranslationalresearch/york-tissue-bank/.

What will happen to the results of any studies using tissue from the tissue bank?
Researchers using tissue collected by the tissue bank will publish and present their results in scientific journals and conferences. Your name or date of birth will never be mentioned in research data presentations or publications. To maintain anonymity, it may not be possible to tell you how your material has been used specifically, however, if you would like to know more about the work resulting from tissue released by the tissue bank please visit https://www.york.ac.uk/cii/clinicaltranslationalresearch/york-tissue-bank/ or contact the tissue bank team using the details on page 5.

What do you do if you discover something new about my condition or health?
It is very unlikely that we will find anything that will directly impact on the care decisions being made in your case. If we do discover something we will feed this back to the medical team looking after you.

Who is organising and funding the tissue bank?
The project is run and funded through a partnership between the University of York and York Teaching Hospital NHS Foundation Trust.
Who has reviewed the Tissue Bank?

The tissue bank has been looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This tissue bank has been reviewed and given a favourable opinion by the Health Research Authority’s National Research Ethics Service Committee (Yorkshire and the Humber- Leeds East, Reference: 15/YH/0016). The tissue bank is monitored by the Human Tissue Authority (HTA) as part of the University of York’s HTA license.

Further information and contact details

For more information about the tissue bank project visit the website

https://www.york.ac.uk/cii/clinicaltranslationalresearch/york-tissue-bank/

or contact the tissue bank:

Tissue Bank Manager: Dr. James Fox, 01904 32 8867
Clinical Lead: Prof. Charles Lacey, 01904 328845
Email: TissueBank@york.ac.uk
CONSENT FORM FOR THE COLLECTION OF TISSUE FOR YORkTissueBank

Tissue Bank Clinical Lead: Prof Charles Lacey

1. I confirm that I have read and understood the patient information sheet, version 4.0 dated 19/10/2017, for the York Tissue Bank. I have had the opportunity to consider the information, ask questions and have had these questions answered satisfactorily.

2. I understand that my participation is voluntary and that I am free to withdraw my consent at any time, without giving a reason and without my medical care and legal rights being affected.

3. I understand that relevant extracts from my medical notes and data collected may be looked at by the tissue bank team, individuals from regulatory authorities, or from the University of York or York Teaching Hospital NHS Foundation Trust, where it is relevant to my donation to the tissue bank and the subsequent research. I give permission for these individuals to have access to my records.

4. I understand that by completing this form I am giving consent for my tissue samples (surplus to clinical requirements) to be collected and stored in the tissue bank for use in research. Including, but not limited to, genetic (DNA and RNA) analysis.

5. I am happy to give a blood sample specifically to be used for the tissue bank (do not initial this box unless you understand that this sample is not for any diagnostic purpose and wish to donate an additional blood sample solely for the tissue bank.)

________________________
Name of Participant

________________________
Date

________________________
Signature

________________________
Name of trained person taking consent

________________________
Date

________________________
Signature

Original to be kept in Tissue Bank file. Two copies to be made, 1 to be given to the participant and 1 to be kept in the participant medical file.

York Tissue Bank patient information sheet and consent form version 4.0, 19/10/2017