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#  Participant Information Sheet

**A University of York service providing human tissue, donated by NHS patients, 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 the research is being done 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 as 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 remaining tissue will be collected for the tissue bank. The tissue taken for the bank would normally be disposed of.

Additional tissue solely for research is never removed from you at any time.

We will also ask you to complete a participant questionnaire that will provide some details about you that may be useful to researchers when they use your samples. These data will be linked with your sample but will be anonymous. 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 from the research team. 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 being removed 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 tissue from the 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 in the research. If you change your mind 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 6.

### 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 may need additional information about you. Factors such as age, treatments and gender can all affect the outcomes of analysis of your tissue. If appropriate, this additional information will be collected from your medical notes by the clinical team but any data will be non-identifiable to the researchers, following research ethics committee (REC) guidelines. All personal information, such as your name and address, is only stored at your hospital Trust. This data is only accessible by the hospital based clinical research team who never sees any research data together with your details. Tissue that is sent to University of York for laboratory research is pseudonymised. Laboratory scientists never have access to personal information, and only data relevant to the tissue given will be released to them. Data is stored securely and confidentially in accordance with legal requirement, any data stored as computer files will be password protected.

### Who is organising and funding the tissue bank?

The York Tissue Bank is funded by the University of York and sample collection is a collaboration between the University and [name of NHS 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 and is approved by the Health Research Authority (National Research Ethics Service) Leeds East Research Ethics Committee (ref: 20/YH/0126). The tissue bank is monitored by the Human Tissue Authority (HTA) as part of the University of York’s HTA license, our license number granted by the Human Tissue Authority under section 16 (2) (e) (ii) of the Human Tissue act 2004 is 12604.

**Privacy Notice**

Any anonymised data that the university collects with your sample will be processed for research purposes under Article 6 (1) (e) of the GDPR (General Data Protection Regulation), which allows:

*Processing necessary for the performance of a task carried out in the public interest*

Special category data is processed under Article 9 (2) (j):

*Processing is necessary for archiving purposes in the public interest, or scientific and historical research purposes or statistical purposes*

Research will only be undertaken where ethical approval has been obtained, where there is a clear public interest and where appropriate safeguards have been put in place to protect data.

In line with ethical expectations and in order to comply with common law duty of confidentiality, we will seek your consent to participate where appropriate. This consent will not, however, be our legal basis for processing your data under the GDPR. Data may be transferred between [name of NHS Trust] and the University of York, in addition data at the University of York may be stored on google storage drives, which are transferred between various countries for back-up purposes.

**General University of York Privacy Notice**

This general privacy notice is for any individual who provides [personal data or special category data](https://www.york.ac.uk/records-management/dp/whatispersonaldata/) to the University of York. It should be read in conjunction with project-specific information.

For the purposes of this privacy notice, the University of York is the Data Controller, as defined in the General Data Protection Regulation. University of York are registered with the Information Commissioner’s Office and our entry can be found at <https://ico.org.uk>; our registration number is: Z4855807.

### What will happen to any samples I give?

Some or all the excess tissue, not required by your doctor, will be sent to the University of York where we will store it. To avoid sample wastage, we may allow researchers from the UK and abroad to apply for access to the tissue for their research. An independent panel 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.

**How do we keep your data secure?**

The University takes information security extremely seriously and has implemented appropriate technical and organisational measures to protect personal data and special category data. Access to information is restricted on a need-to-know basis and security arrangements are regularly reviewed to ensure their continued suitability. No patient identifying data will be stored at the university, this will be held at the hospital. Any data associated with the sample will be held digitally on password protected computer systems. For further information see, <https://www.york.ac.uk/it-services/security/>.

### 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 say how your material has been used specifically. However, if you would like to know more about the work resulting from material please contact the tissue bank team using the details below.

**How long will we keep your data?**

The University will retain your data in line with legal requirements or where there is a business need. Retention timeframes will be determined in line with the University’s Records Retention Schedule, though for research data this is normally around 10 years.

**What rights do you have in relation to your data?**

Under the General Data Protection Regulation, general right of access to your data, a right to rectification, erasure, restriction, objection or portability. You also have a right to withdrawal. Please note, not all rights apply where data is processed purely for research purposes. For further information see: [https://www.york.ac.uk/records-management/generaldataprotectionregulation/individualsrights/](https://www.york.ac.uk/records-management/generaldataprotectionregulation/individualsrights/%C2%A0%C2%A0)

**Questions or concerns**

If you have any questions about this privacy notice or concerns about how your data is being processed, please contact the Tissue Bank Manager: human-tissue@york.ac.uk in the first instance. You can also contact the University’s Data Protection officer at: dataprotection@york.ac.uk.

**Right to complain**

If you are unhappy with the way in which the University has handled your personal data, you have a right to complain to the Information Commissioner’s Office. For information on reporting a concern to the Information Commissioner’s Office, see [www.ico.org.uk/concerns](http://www.ico.org.uk/concerns).

### Further information and contact details

For more information about the tissue bank project visit the website <https://www.york.ac.uk/biomedical-research-institute/clinical-and-translational-research/york-tissue-bank/> or contact the tissue bank:

Tissue Bank Manager: Dr Jenny Baker, 01904 328521

Designated Individual: Professor Ian Hitchcock, 01904 328914

Email: human-tissue@york.ac.uk

## CONSENT FORM FOR THE COLLECTION OF TISSUE FOR

Tissue Bank ID:

Designated Individual: Professor Ian Hitchcock

Please **initial** box

1. I confirm that I have read and understood the patient information sheet, version 4.5 dated 19/09/2023, 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 research team, individuals from regulatory authorities, or from the University of York or [the participating NHS 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 conducted at the University of York, other universities or commercial partners.
5. I understand that my tissue samples may be used for genetic (DNA and RNA) analysis conducted at the university of York, other universities or commercial partners.
6. 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.)

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Name of Participant Date Signature

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Name of trained person taking Date Signature

consent

***Original to site file; Copy to donor/medical records.***