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Information For Patients & Healthy Volunteers

**Guy's & St Thomas'
Research Biobanks**

**Donating cells and tissue for research,
to improve health care**

The aim of this booklet is to answer questions you may have about why we ask patients and healthy volunteers to donate cells or tissue to our research biobanks and what it will involve.

Research biobanks

Many hospitals and universities, including Guy's & St Thomas' NHS Trust and King's College London, have created biobanks to help with research into different diseases. At Guy's and St Thomas', these include a cancer biobank, which stores tissue, blood and other body fluids from patients who have a possible or confirmed diagnosis of cancer, as well as patients and healthy volunteers who do not.

Research biobanks must meet the terms of all current laws and ethical guidelines associated with tissue collection and use for research. This includes having a Human Tissue Authority licence and approval from a Research Ethics Committee. All tissues, cells and data are stored with a code number replacing personal details. Senior doctors, scientists, and independent representatives, including patient representatives, manage research biobanks.

The biobanks are able to collect and store cells and tissue in ways that are suitable for many different types of research. In particular, some research cannot be done on the tissue blocks used for diagnosis but need specially collected tissue that the biobank can prepare and store.

It is a condition of being given donated tissues that research results are shared to maximise their value. This is done by publishing results in medical or scientific journals and also sharing results directly with different researchers.

The East of England – Cambridge East Research Ethics Committee has approved and will regularly review the Guy's & St Thomas Research Biobank (REC Ref 22/EE/0005)

What is meant by cells and tissue?

Cells are the basic units from which our bodies are made. They perform all of the functions we need. Cells can work as single units or combine to make tissue. Good examples of cells working as single units are red and white blood cells, which we often investigate when doing blood tests.

However, most cells in our bodies are organised into tissue. In tissue, a mixture of cell types exist together to carry out a particular job for your body. Most tissues within your body are organised into organs - for example, your breast, lung, throat, stomach or prostate.

Individual cells from these tissues may be tested in procedures such as a cervical smear test. Tissues may be sampled for diagnosis by taking a

biopsy, or removed as whole organs (or parts of organs) during surgical operations.

The information in this leaflet does not apply to tissue removed at post mortem (after death) examination, for which there are separate arrangements.

Why are cells and tissue donated by patients vital for research?

Human cells and tissue are vital for medical research. Scientists use them to:

- learn how diseases start and progress.
- identify cell characteristics to be even more certain that a particular treatment will be effective.
- observe effects of new drugs and tests before clinical trials begin with volunteer patients.

Research may lead to new tests, better treatments for diseases such as cancer and ways of detecting diseases earlier. It may take place in the UK, or overseas in international partnerships. For most research, cells and tissue can only be used if you have given your permission.

How are cells and tissue collected?

We collect cells and tissue from people during a range of procedures. For example:

- blood tests
- cheek scrapes
- operations
- biopsies (removing a tissue sample for examination).

This is done as a normal part of investigating and treating illness.

Cells and tissues are examined by a pathologist to help make a diagnosis. Once tissue has been selected for this, any remaining cells or tissue that the pathologist doesn't need can either be kept for research (with your permission) or be disposed of. The surplus cells and tissue for research are collected in a research biobank.

Even if you agree to donate these samples, we rarely use all of the tissue for research. It is necessary to do so in some clinical trials of new treatments, with your specific permission. However, we try always to keep some tissue in

reserve in case it is needed for further diagnostic tests if you become unwell again or if new treatments are developed.

For some research, we may also wish to obtain extra samples of blood or tissue from you purely for research. We usually ask for 40ml (about 8 teaspoons) and occasionally 80ml (about 4 tablespoons) of blood and a few tiny pieces of tissue (for example, needle cores 1mm wide by 10-15mm long). The exact amount of blood or tissue we would like will always be discussed with you before the procedure. Any extra tissue pieces will usually be taken as part of a planned diagnostic biopsy/procedure. Occasionally, we may ask if you are willing to undergo an additional small biopsy procedure before or during treatment, which is unrelated to your care. The research tissue collected, is used to help develop new methods of predicting the effectiveness of a treatment. Your hospital doctor will discuss the procedure and you will be given plenty of time to decide. If you are willing to undergo a biopsy procedure you will be asked to complete a consent form for both the procedure and for the Biobank.

We may also ask you for saliva, urine or faecal (stool) samples. We will discuss how these are collected and if you agree, provide you with an appropriate container or kit.

Occasionally, we may also ask healthy volunteers to provide blood, urine, saliva, cheek scrapes or faecal samples. These may be patients who do not have an illness, such as those undergoing hip replacement or tooth extraction. As well as family members, friends, and carers.

Do we need consent to use patients' cells and tissue?

Yes. To use cells and tissue for research we have to ask for consent. This is a requirement of current law; the Human Tissue Act 2004. We normally do this when your first tissue or blood tests are done. At that time, we also ask if you agree for us to keep leftover material from any future samples taken for testing during your treatment and follow-up. If you have had tests in the past with cells or tissue leftover, either at Guy's & St Thomas' or at another Hospital, we usually ask for your consent to use these too.

Do I have to allow my cells or tissue to be kept and used for research?

No. It is entirely your choice whether you allow the Trust to keep your cells or tissue for possible future research. Your treatment, diagnosis and all other

aspects of medical care will not be affected in any way, whether you agree to this request or not.

Also, if you change your mind later, you are free to withdraw consent at any time and do not have to give a reason. If you inform the doctor caring for you that you wish to withdraw your consent, any remaining samples of your cells or tissue held by the biobank at that time will be disposed of according to our routine procedures. Although we will immediately stop using your cells or tissue, we cannot undo any research that has already been done.

If you agree that we can use leftover tissue from future tests, we still check that this is your wish each time you have a biopsy or surgery to remove tissue. You can change your mind at any time and we will make sure that your wishes are followed – you just need to tell the clinical staff looking after you.

We will always ask for your consent every time we wish to obtain extra samples of blood or tissue from you purely for research, but you may not need to complete a consent form each time.

Will my personal information (data) be used?

It is often important for researchers using cells and tissues to know something about the medical history of the donor. We ask you for your permission to get relevant information from your medical records and provide this to researchers when requested. Information provided to researchers will always be anonymised. With your permission we will check your medical records at regular intervals for updates and will continue to do so while we still store your samples.

Biobank staff gather the information in strict confidence. They will follow all current rules applying to patient confidentiality, data protection, transfer and storage.

How long will you keep my stored cells and tissue for research?

We will store your donated cells, tissue, blood and other bodily fluids until they have been exhausted by researchers. Samples may be kept for many years. If your donated samples can no longer be used for research, they will be disposed of in accordance with hospital policy.

Who can use my stored cells, tissue and data for research?

- Researchers of this Trust and of other hospitals, medical schools and universities (including overseas researchers) can apply to use the stored tissue and cells.
- Scientists from drug companies and biotechnology companies, who may be based in the UK or abroad, may also apply if they are working in partnership with a local hospital or university researchers to validate new cancer drugs and tests.

Any of these researchers or scientists can apply to use both anonymised tissue and data stored by the biobanks. Applications are evaluated by an Access Committee, which consists of senior consultants and scientists from King's Health Partners, as well as external specialists and lay members. Only projects that add to our knowledge about the disease or its treatment will be approved.

Anyone wishing to use the tissue or cells and data for research must provide evidence that their research meets all current legal and ethical requirements. Organisations must also complete a contract (material and data transfer agreement) with the Trust which outlines exactly what the tissue and data can be used for and how it must be looked after. Researchers are contacted to find out how they have used the materials and whether this work has been published.

Will anyone make a profit from my stored cells and tissue?

Cells and tissues will only be used on a non profit-making basis. Your donation is a gift and we cannot give you any payment for allowing your cells or tissues to be used for research.

Researchers may be charged an administrative fee when they obtain material from the biobanks, to cover the costs of preservation, storage, transport, and documentation.

Will my cells or tissue be used for research involving animals?

Studies using human tissue in animals remain essential for some medical research, although these are kept to a minimum. Animal research is strictly regulated by law to ensure that animals are only used when there is no alternative and to protect their welfare when used. Donated cells and tissue may occasionally be used in such studies:

- Directly (e.g. cancer cells or tissue transplanted into a mouse in order to test a completely new treatment without risking harm to patients).
- Indirectly (e.g. DNA from human cells introduced into animal cells to study the function of human cancer genes).

Will my cells or tissue be used to create cell lines or organoids?

Scientists are able to separate individual cells from a piece of tissue and keep these alive in the laboratory. These cells can grow and multiply, creating either a 2-dimensional cell line or 3-dimensional organoids, which resemble miniature organs. Most cells have a limited lifespan even as cell lines, but some cancer cells do not and can be kept for research indefinitely.

Cell lines and organoids can be used to study how cells react to potential new treatments without risking any harm to a patient.

Will my cells or tissue be used for genetic research?

Cells and tissue may be used for genetic research which is the study of DNA/genes to look for abnormalities that may increase the risk of disease or affect the way a patient may respond to treatment. Current research is heavily involved in discovering ways in which the DNA/genes in human cells affect how they become diseased. If we can find out what causes disease, we can better detect and treat them.

To guarantee confidentiality, as with all other studies using cells or tissue and data that we collect, researchers will only identify the cells, tissue and data with a code number, not your personal details. Many different research studies are needed, using samples from many individuals, before we can understand the importance of any single genetic abnormality.

Because of this, the biobank will not pass on to patients or their doctors the results of genetic research done using cells or tissue.

What if new information about my health is discovered during research using my cells or tissue?

Information discovered during research is not usually directly relevant to an individual's healthcare. You will not normally hear any details about research studies that your cells, tissue or data have been used for.

However, if any information comes to the biobank's attention that could affect your treatment directly, a member of Biobank staff will unlock the code number and pass details on to the doctor in charge of your care. The researcher providing the information will remain unaware of your identity.

What should I do if I want to allow my cells, tissue and data to be used for research?

If after reading this information leaflet you agree that your cells or tissue and data can be donated to the research biobank, please make sure that you complete and sign the Biobank consent form.

You may be approached for consent when you attend your clinic appointments at Guys and St Thomas' Hospitals where the doctor, nurse, biobank coordinator or trained biobank volunteers will show you how to complete the form and where to sign. You may also receive a telephone call for virtual consent, where you will be taken through the form and offered various options to review and sign, including:

1. Receiving a PDF copy of the consent form via email to sign electronically or print at home, sign, and email back.
2. Receive a printed copy of the consent form via post to sign and return in a prepaid envelope.
3. Sign when attending your next hospital appointment.

What if I do not want my cells or tissue to be used for research?

If you do not wish your cells or tissue to be kept for use in medical research, then do not complete or sign the consent form asking for your agreement to this

Do I have to agree to everything?

No. If you feel uncomfortable with certain sections on the consent form you do not need to agree to these. You can choose what samples to donate and how they might be used. However, we do need your consent to both store your surplus samples and access your medical records in confidence to be recruited into the Biobank.

Who can I ask if I have further queries on this subject?

Staff of this Trust aim to provide the best possible service for patients' healthcare and will be happy to answer any questions that you may have.

If you wish to ask more detailed questions about cell and tissue storage for research, please speak first to a member of the medical team caring for you. Should you wish to phone or write, the Trust's contact details are on the back page of this booklet. For more general information, you may wish to contact the Patient Advice and Liaison service (PALS).

Further information

Guy's and St Thomas' NHS Foundation Trust

To contact staff at the Trust directly, please write to your clinical consultant at:
St Thomas' Hospital
Westminster Bridge Road, London SE1 7EH

Guy's Hospital
Great Maze Pond, London SE1 9RT

(switchboard) 020 7188 7188

www.guysandstthomas.nhs.uk

Knowledge & Information Centre (KIC)

For information about health conditions, support groups and local services, or to use the internet and send emails, please visit the KIC on the Ground Floor, North Wing, St Thomas' Hospital.

tel: 020 7188 3416

email: kic@gstt.nhs.uk

PALS

To make comments or raise concerns about the Trust's services, please contact our Patient Advice and Liaison Service (PALS). Ask a member of staff to direct you to PALS:

tel: 020 7188 8801

email: pals@gstt.nhs.uk

NHS 111

Offers health information and advice from specially trained nurses over the phone 24 hours a day.

tel: 111

Language support services

If you need an interpreter or information about the care you are receiving in the language or format of your choice, please get in touch using the following contact details:

tel: 020 7188 8815

email: languagesupport@gstt.nhs.uk