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Lothian NRS BioResource

Participant Information Sheet Information for the collection of Tissue, Biospecimens and Data for Research Version 1.4

You are being invited to donate tissue samples to the Lothian NRS BioResource. Before you decide whether or not to do this, please take time to read the following information carefully and talk to others such as family, friends, your GP or healthcare team about the study if you wish. Please contact us if there is anything that is not clear or if you would like more information.

What is the purpose of the study?

The Lothian NRS BioResource is funded by the CSO (Chief Scientist Office) which is part of the Scottish Government Health Directorates. This is a collaboration which has been set up between Scottish Universities and Health Boards. Its aim is to help translate discoveries made in research laboratories into improved care for patients.

The Lothian NRS BioResource will collect and store **biospecimens** (small pieces of tissue, cells and samples of body fluids) and build up a collection for use in research and education. This BioResource is being run by NHS Lothian, and has been approved by a Research Ethics Committee. The samples will only ever be used in research applications which have been approved by a scientific review committee.

What is tissue and why is it required for research and education?

The human body is made up of cells which are the basic building blocks for tissues. Organs such as lungs, liver, kidney and appendix are made up of tissue. There are many different types of cells and tissues in the human body. Body fluids such as blood, urine and saliva contain cells. Material taken during a cervical smear test also contains cells. Doctors and scientists need human tissue and other biospecimens for medical research. From these they can see and understand how diseases start and develop. They can also try out different drugs and tests on the tissue. This may help them find new medicines and treatments, and possibly even ways of diagnosing diseases earlier.

As well as providing care and treatment for patients, the NHS is also responsible for educating and training doctors, nurses and other healthcare workers. Human tissue is needed for this as well.

Why have I been asked to take part?

You are currently in hospital or attending a clinic and may be due to have an operation or medical procedure during which you may have some cells or tissue removed. If some cells or tissue are left over, and you agree, we would like to use this material for research.

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What will this involve?

During your investigation(s) or operation(s), which are part of your treatment the doctor may take some tissue from your body. This piece of tissue will be sent to a pathologist for diagnosis. A pathologist is a doctor who specialises in the examination of tissue, to diagnose or confirm what is wrong with you. Some of the tissue is used for your tests, and then becomes part of your medical record. This means that it can be looked at again if you are ill in the future.

However, some tissue is usually left over and would normally be disposed of. We are asking you to donate this surplus tissue for medical research and education.

During your treatment, the doctor may also take body fluids e.g. blood and urine for testing. Some of these may also be “left over” and if you agree, could also be used for medical research and teaching.

We may ask you to provide us with an extra blood sample, and this could possibly mean an extra venepuncture. We may also ask you to provide a urine sample.

We would also like to use some information from your medical notes. This will be information about your physical condition, treatment and diagnosis but not about your mental health.

Your name and address and anything else that could identify you will be removed before allowing researchers to use any of your samples or data.

Do I have to do this?

No, it is entirely up to you if you want to donate to the BioResource. When you come into hospital or attend a clinic and we ask if you agree to let us use your surplus tissue for education or research, simply say no. We will not put you under any pressure, and you do not have to give a reason. **Please be assured that your decision will not affect your healthcare.**

You can also change your mind at any time, without giving a reason. If you change your mind later on however, some of your samples may already have been used. It would be too late for us to stop your sample being used, but we would dispose of any tissue that hadn't been used yet.

What are the benefits of taking part?

It is unlikely that you will personally benefit from the research. This research often involves testing large numbers of samples from many different people to try to identify factors that influence medical conditions and disease, and it can take many years to produce advances in treatment. However, if at any point during the programme this information becomes of use in guiding your treatment, the clinical care team looking after you in the hospital will be made aware of this and they will explain the information to you

You can benefit from the knowledge that you are personally helping research to prevent or treat illness. The tests and treatments being used for you were developed with the help of patients who took part in research years ago. Research might make faster progress as more human samples are studied, helping the health of future generations

What are the possible disadvantages or risks of taking part?

The only risks would be the possibility of some pain or bruising from giving an extra blood sample. Otherwise, there will be nothing extra happening to you as the BioResource would only collect and store tissue that would normally have been removed and disposed of anyway.

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Where will my tissue sample be used?

- The NHS
- Universities
- Research Institutions
- Commercial companies

Tissue samples may also be sent abroad. You can be sure, however, that all researchers whether in this country or abroad must have proof that they are following legal and ethical guidelines for their research. Researchers working abroad will be required to sign a form agreeing to follow the same rules and regulations which apply in the UK.

Your donated tissue will not be used in animal research, research about termination of pregnancy, or reproductive cloning.

How long will tissue be stored?

The tissue you donate will stay in the NHS, or with approved researchers until it is all used, or disposed of should you decide to withdraw your consent. All tissues will be disposed of lawfully and respectfully, and a record will be kept of this. If you decide to withdraw consent, you can tell a member of your healthcare team, or contact us at the BioResource on the telephone number or email address in the “Further Information” section.

Will my taking part be confidential?

Yes, only the BioResource staff will be able to identify you. They will abide by the Data Protection Act 1998 at all times and make sure your name, address, and any other information that would identify you are removed from your medical information before it is given to any researchers. The information held on computer will be kept secure, and all written information will be held in locked filing cabinets.

Will my medical notes be used?

Medical research is of more value if the researcher has information about the medical history of the person who donated the tissue. We would like your permission to use and store information from your medical notes now, and possibly in the future as a follow up. All information collected and stored will be kept strictly confidential. Your personal information like your name and address will be removed from your medical notes before being given to anyone for their research. Only the BioResource staff and your Healthcare team will be able to link your information to your medical notes.

Can researchers find new information about my health?

It is possible, but the research on your tissue will normally have nothing to do with your own care or treatment. Future research may give us information about what type of treatment would be most suitable for particular medical conditions but this data is primarily intended for research and it is very unlikely that your sample alone will give us this type of information. However, if any information might be of use in your clinical care, the doctors looking after you may discuss how the information could be used to guide your treatment.

Will researchers carry out genetic tests on my tissue?

Genetic testing including DNA testing may be carried out on your donated tissue. These tests may include whole genome sequencing. Whole genome sequencing means studying the complete pattern of the DNA to help understand the biology of genes. If whole genome sequencing was carried out on your sample, this would be a research test and not a clinical test, and no results would be fed back to you unless your doctor felt it would improve your treatment

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in some way. A lot of research today focuses on the study of genetic material from healthy individuals compared to people with known diseases. This comparison helps researchers to discover genetic differences which in turn help in the development of new drugs and treatments.

Will anyone make money from my tissues?

It is illegal to sell tissue for profit. The NHS may charge researchers a fee for your tissue, but this is to cover the costs of running the BioResource.

If researchers develop a new drug, treatment or test, a pharmaceutical company or other researcher may then make a profit. It will not be possible to claim any money because you donated tissue, but any new drug, treatment, or test would potentially help us all in the future.

I want to donate...what should I do next?

When you come into hospital or attend a clinic, you will be asked if you agree to let your surplus tissue from any investigation(s) or operation(s) be used for medical research. You will then be asked to sign a consent form. You should keep a copy of this Patient Information Sheet and Consent Form for your records.

What if there is a problem?

If you believe that you have been harmed in any way by taking part in this study, speak to the research team in the first instance. If you are still unhappy, you have the right to pursue a complaint and seek any resulting compensation through NHS Lothian which is acting as the research sponsor. Details about this are available from the research team. Also as a patient of the NHS, you have the right to pursue a complaint through the usual NHS process. To do so, you can submit a written complaint to the Patient Liaison Manager, NHS Lothian Complaints Office, 2nd Floor, Waverley Gate, Edinburgh telephone 0131 465 5708. Note that the NHS has no legal liability for non-negligent harm. However, if you are harmed and this is due to someone's negligence, you may have grounds for a legal action against NHS Lothian, but you may have to pay your legal costs.

Who has reviewed the study?

The East of Scotland Research Ethics Committee 1 has examined the proposal and has raised no objections from the point of view of medical ethics. It is a requirement that your records in this research together with any relevant medical records, be made available for scrutiny by monitors whose role is to check that research is properly conducted and the interests of those taking part are adequately protected.

Further Information

If you have any questions about the donation of samples and information on the possible uses of them, please ask the person discussing donation with you and seeking your consent. If you think of anything else later, you can contact us at 0131 465 5456, Public Health Office, NHS Lothian, Waverley Gate, Edinburgh, or email rie.tissuegovernance@luht.scot.nhs.uk

We will try to supply this information in different languages and formats if requested.

Thank you for taking the time to read this Information Sheet and for considering taking part in this study.

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