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Lothian NRS (NHS Research Scotland) BioResource

Participant Information Sheet Information for the collection of Tissue, Biospecimens and Data for Research Version 1.6

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 part of a collaboration between Scottish Universities and Health Boards to help translate discoveries made in research laboratories into improved care for patients.

The Lothian NRS BioResource does this by collecting and storing **biospecimens** (small samples of tissue, cells and body fluids) and releasing these for approved scientific and medical research projects and medical education. The tissue samples are even more useful for this purpose if they have some depersonalised patient data linked to them. This BioResource is run by NHS Lothian, and has been approved by a Research Ethics Committee. The samples will only ever be used in research and medical education projects 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 these samples and patient data for medical research to 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 an appointment or clinic and may be due to have a 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 and/or medical education.

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What will this involve?

During your treatment now and possibly in future, the doctor may take some tissue, blood or other fluid from your body. This sample may be sent to a laboratory for diagnosis and/or testing.

Some of the tissue is used for your tests, but some of the sample is often left over and would normally be disposed of or stored as part of your medical record. We are asking you to consider donating this surplus tissue for medical research and education.

On some occasions we may ask you to provide us with extra blood samples, and this could possibly mean an extra venepuncture on some occasions. A venepuncture means the use of a needle to remove blood from your vein) Even if you consent to this, you can say no at any time. We may also ask you to provide a urine sample.

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

Do I have to do this?

No, it is entirely up to you whether you want to donate to the BioResource. When we ask if you agree to let us use your surplus sample and data 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 and depersonalised patient data collected for the research may already have been used. It would be too late for us to stop this, but we would dispose of any tissue that hadn't been used yet. We would also dispose of any patient data collected and stored for the research but would keep a small amount of data about your wishes to withdraw consent. This would be a copy of your consent form with "consent withdrawn" written on it and a copy of any letters we may send you confirming withdrawal.

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.

What are the benefits of taking part?

It is unlikely that you will personally benefit from the research. Research usually 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 may explain the information to you

What are the possible disadvantages or risks of taking part?

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

Where will my tissue sample be used?

- The NHS
- Universities
- Research Institutions
- Commercial companies

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Tissue samples and depersonalised data 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. 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 BioResource, 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. Your sample may be used up right away or may be stored for several years. Whether it is stored for future research or used for research immediately, it will be de-identified and given a study code.

Will my taking part be confidential?

Yes, only the BioResource staff and delegated staff working in conjunction with the BioResource to prepare and deliver the samples and depersonalised data for research will be able to identify you. They will abide by the General Data Protection Regulation (GDPR) and Data Protection Act 2018 at all times and make sure your name, address, and any other information e.g. your CHI (Community Health Index) number that would identify you are removed from your patient data before it is given to any researchers. Your depersonalised data will be held on NHS approved computers and will be kept secure. All written information will be held in locked filing cabinets.

Further information on how your patient data may be used for research can be found on the NHS Health Research Authority website -<http://www.hra.nhs.uk/information-about-patients/> or we will be happy to provide you with a paper copy on request.

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 some patient data from your medical notes now, and possibly in the future as a follow up. All patient data collected and stored by our team for research will be kept strictly confidential.

Can researchers find new information about my health?

It is possible, but the research on your tissue may 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 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 and any disease related changes. If whole genome sequencing was carried out on your sample, this would be a research test and not a clinical test, which means no results would be fed back to you unless your doctor felt it would improve your treatment 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.

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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 could 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 or other appointment, you may be asked if you agree to let your surplus tissue from any investigation(s) or operation(s) along with some patient data 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 clinical team or contact the BioResource 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. 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 Experience Team, Waverley Gate, 2nd Floor, 2-4 Waterloo Place, Edinburgh, EH1 3EG. Telephone 0131 536 3370 or email feedback@nhslothian.scot.nhs.uk. 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 BioResource application and has raised no objections from the point of view of medical ethics. It is a requirement that your records kept as part of this research, 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 properly 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 asking if you are willing to 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@nhslothian.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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