Barts Health
NHS Trust

PATIENT Information Sheet
Barts BioResource Health Data and Sample(s) Donation

(such as blood/saliva/swabs/urine/faeces and/or soft/solid tissue samples)

Information for patients for the Barts BioResource

Introduction

You have been treated at Barts Health NHS Trust. At that time, you were unable to decide for whether to participate in this research, the term for this is that you "Lacked Capacity".

We approached a Nominated Consultee i.e. a medical professional who is independent of the study and is familiar with the nature and risks of participation in the Barts BioResource. We asked them to consider if was legally and medically appropriate for you to join the Barts BioResource as a patient. Their decision did not affect the standard of care they receive in any way.

We also approached your relative/friend for their opinion whether or not you would want to be involved. We asked them to consider what they knew of your wishes and feelings, and to consider your interests. We also asked them to let us know of any advance decisions you may have made about participating in research.

The joint decision was to enrol you in the Barts BioResource.

As you have now improved and are able to make these decisions for themselves, we are now consulting with you.

We will now explain what has happened and why. At this time, you are to either give you Informed Consent or withdraw from the study with no effect on the standard of care that you will continue to receive.

If you are unsure about any of this you may seek independent advice.

<u>The following information is exactly the same as that provided to your relative/friend AND The Nominated Consultee.</u>

What is the Barts BioResource?

The purpose of the Barts Bioresource is to allow research into health and diseases. The Barts Bioresource is supported by the National Institute for Health Research, which is part of the National Health Service (NHS). The Barts BioResource will be very valuable because it will help us to find new ways of identifying, treating and preventing diseases.

What are we asking you to do?

We would like to invite you to consider joining the Barts BioResource whilst you are attending a normal outpatient appointment or receiving treatment at the hospital. You are being asked this because you are a patient of Barts Health NHS Trust and the aim is to collect healthcare information for the Barts BioResource from as many patients as possible. You are also asked to consent to be included in the Barts BioResource for future research opportunities.

We are asking permission to collect and store any tissue removed as part of your procedures or surgery which would otherwise be disposed of. These samples will be processed and labelled with a generated code number (not your name) and these will be stored in a secure freezer.

If you undergo heart surgery, we may ask you to donate a special type of tissue. The upper chambers of the heart (atria) have extra tissue, termed the atrial appendages. These have no known function and are often removed during cardiac surgery routinely. We will plan to collect a sample (biopsy) from these sites, which is safe to do and does not have any defined risk above that of your surgical procedure. This will only be performed if they are not being removed anyway.

If you undergo another type of surgery or procedure, we may wish to collect a tissue sample (biopsy) if considered safe to do and only if considered not to increase the risk of your clinical procedure. Specific details regarding this tissue collection will be noted in your patient record as part of the consenting process.

We may also invite you to consider donating biological sample(s) (up to 50ml of venous blood samples, saliva, throat, buccal and/or nasopharyngeal swabs, urine, faeces and soft/solid tissue samples). The aim is to collect these samples for the Barts BioResource from as many patients as possible.

What will happen if you say yes?

The first thing you need to do is give your permission (consent) by signing this Consent form: Health Data and Samples Donation which we have provided – this will be either on paper or electronically as is most practical. Please keep this information leaflet to remind you what we have asked you to do.

If you agree to take part:

- Our research team may ask you some questions about yourself. We also ask if they can have permission to look at your medical records to obtain information about your health, any tests you may have had in hospital, any other diseases which you or your relatives may have, and your past treatment. Data collected about you will be stored on a secure Barts BioResource database accessible only to Barts BioResource staff.

- Our research team may also want to contact you via phone or post, or electronically (email) if they have additional inquiries. Although email is highly convenient, it may be less secure than other contact methods. There is a small potential risk that any individually identifiable health information and other sensitive or confidential information that may be contained in such email could be misdirected, disclosed to or intercepted by unauthorised third parties. In light of this, we ask for your specific permission if you prefer to be contacted by email.
- From time to time we may approach you to ask if you would read and complete questionnaires relating to aspects of your health and quality of life. Other questionnaires may relate to your experiences of the hospital, your treatment and care. We will ensure that these are not frequent and that they would not exceed more than 25 minutes at a time. Of course, you do not have to respond to any of these questionnaire requests as they are optional.
- Our researchers anticipate that the research programme will benefit from following up your medical health status and thus may wish to contact your GP/hospital or other NHS data holders such as NHS digital at periodic intervals for updates relating to your health.
- It is possible that we may invite you for a follow-up appointment at a later date to help us with our research but this is unlikely and your participation in this would be completely voluntary.
- If you undergo a clinical scan (such as MRI, ultrasound, echocardiogram, electroencephalogram or similar monitoring/measuring modalities), we may add a maximum of 10 minutes at the end of the clinical scan. This will help test and/ or develop new imaging techniques. The additional scanning is not associated with radiation and will not cause harm to you, we will not do this with scans that would require exposure to x-rays (e.g. CT scans).

Sharing of information and the General Data Protection Regulation (GDPR)

- Barts Health NHS Trust is the legal Sponsor for this study based in the United Kingdom
- We will be using information from your healthcare records in order to undertake this study and Barts Health NHS Trust is the Data Controller for the Barts BioResource.
- Researchers who have entered into a Material Transfer Agreement with the Barts BioResource will be joint data controllers with Barts Health NHS Trust. This means that we are responsible for looking after your information and using it properly. Barts Health NHS Trust will keep identifiable information about you for up to 5 years after the study has finished.
- Should an external platform be used in the future, this will also become a data processor or controller (to be determined on a case by case basis considering the particulars).
- Your rights to access change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible

- All your personal details are kept strictly confidential and are de-identified in the research process. This means that personal information such as your name and address are removed prior to sharing or use of data or samples.
- In order to maximise the benefit that can be derived from the information and samples we collect, researchers may share de-identified healthcare information, blood, saliva, swabs, urine, faeces or tissue samples with researchers in other hospitals, universities or research institutes or associated delivery organisations. Any medical information or samples shared in this way will be coded and will not be labelled with personal information such as your name and address.
- These organisations may be outside the UK or the European Union. Health data and samples can be very helpful in designing new treatments and/or medications. It is possible that your health data could be used in a study with or by a commercial organisation (such as a company manufacturing a drug). Any information shared with commercial organisations would be coded and not contain information such as your name or address.
  It is possible that your images and some clinical information will contribute to a large database which will be available to the public for research, education and teaching purposes. This may include details such as age, gender, height, weight, blood pressure, smoking, ethnicity and medical conditions as far as available. All personal details such as your name or anything that might identify you will be removed from your images and clinical information. The de-identified data may be placed on publicly accessible Web sites. You can find out more about how we use your information at:

  https://bartshealth.nhs.uk/privacy

- Your information could be used for research in any aspect of health or care and could be combined with information about you from other sources held by researchers, the NHS (e.g. primary care data from your general physician, NHS Digital or Healthcare Quality Improvement Partnership = HQIP) or United Kingdom government.Where this information could identify you, the information will be held securely with strict arrangements about who can access the information. The information will only be used for the purpose of health and care research, or to contact you about future opportunities to participate in research. It will not be used to make decisions about future services available to you, such as insurance or your clinical care.
- Where there is a risk that you can be identified your data will only be used in research that has been independently reviewed by an ethics committee.
- If you agree to take part, the access to your health information will be treated confidentially and could help research to benefit those affected by diseases

Tissue and blood collection

- Whilst you are attending the Barts Health NHS Trust for your planned surgery, medical procedure or clinical reviews you may be asked to donate your biological samples which might include tissue, (blood (up to 50mls), saliva, throat, buccal or nasopharyngeal swabs, urine, faeces and soft/solid tissue samples). Not all samples will be collected, and will be based upon your wishes and instructions on the day. We may ask you to provide and return

to us samples (e.g. saliva) in appropriate containers that we will send to your address if you agreed to this.
- We will also retain any samples which have been collected for your clinical care and are of no future use and would otherwise be discarded and destroyed.
- These samples will be processed and labelled with a code number (not your name) and these will be stored in a secure freezer.
- In future appointments we may ask you if you are still happy for us to take additional biological samples (such as blood, throat, buccal or nasopharyngeal swabs, urine, faeces or tissue). You are under no obligation to provide further samples. The reason we may ask for further samples is that for some research studies it is beneficial to have samples from the same person at different time points.
- Your data will be stored for a period of up to 5 years. Biological samples including tissue will be stored for a period of up to 10 years. If there are any unused samples after this time, a decision will be made either to keep the remaining samples or dispose of them.
- After a period time the coded biological sample(s) including tissue you have provided may be passed on to our researchers for use in one or more approved research studies which will have the aim of helping doctors identify, treat and prevent diseases.
- It is possible that your coded biological sample(s) including tissue may be used for genetic research to help us understand the genetic basis of health and disease. The results of these investigations are unlikely to specifically affect your care and will not be of diagnostic quality and so will not routinely be reported back to you. However, it is possible, though very unlikely, that the genetic research tests we perform using your blood will lead us to identify an abnormal gene which sometimes can run in families. If we believe that an abnormal gene is important for your health or that of your family, we will call you back to explain what we have found and offer support and advice. Only the Barts BioResource Research team will have access to the sample coding and will be the only members of staff apart from your clinicians who will approach you.
- It is possible that your sample(s) may be used in animal research, as this is an essential tool for the development of medical treatments and the understanding of human disease.
- Your sample(s) will NOT be used for research that involves Reproductive Cloning.

If you agree to take part, the donation of your biological sample (s) including tissue will be treated as gifts that could help research to benefit those affected by diseases and health conditions.

What happens if you say no?

You are free to say no – the choice is yours. Your decision will NOT affect the standard or type of treatment you will receive from the hospital or doctors, now or in the future. If you say no, we will not collect any research samples.

What happens if you say yes but then decide to change your mind later on?

You can change your mind at any time – you can let us know using the contact details at the end of this information sheet.

If you tell us you have changed your mind, all biological samples including tissue in storage will be destroyed in the way human samples from hospitals are normally destroyed. The research information about you will be deleted so it cannot be used again.

If you change your mind after a long time, the samples may have already been used. We cannot recall samples or information from researchers once they have been used. If, by then, your gift has already helped create new knowledge, that information cannot be undiscovered and will contribute to medical understanding. However, we will dispose of any remaining samples and the research information so your gift will not be used in any further research.

What are the benefits to you?

It is unlikely that you will personally benefit from the research as it usually takes many years for advances to be made which help the way diseases and health conditions are identified, treated and prevented.

You can benefit from the knowledge that you are personally helping research to find out new ways of identifying treating and preventing disease. The tests and treatments you have received were developed with the help of patients who took part in research years ago. We believe research will make faster progress as more human samples are studied. Also, by using human samples the need to use animals in research may be reduced.

What are the risks to you from giving research biological samples including tissue sample?

There are no significant risks associated with giving a biological samples or a tissue biopsy. Sometimes giving a blood sample can cause slight bruising but this is uncommon. Tissue biopsies are only taken if it is safe to do, and normally involves collecting tissue being removed anyway as apart of a clinical procedure. If a biopsy is being taken in addition to your clinical procedure, the research team will let you know and document these details in your patient records.

Who will be able to access your biological samples including tissue?

The Barts BioResource is managed by experienced doctors and scientists who will ensure that your samples are only made available to those researchers who need to have access for an approved research study. Samples used by scientists will be coded so that they do not know who you are. Everyone handling your personal and medical details will be bound by a professional and legal duty to protect your privacy. When research studies are published, they will not contain your personal details (such as your name, address, phone number) and it will not be possible for anyone else to identify who you are.

Do you receive payment for donating biological samples including tissue to the Barts BioResource?

You will not receive any payment for giving biological sample(s) including tissue to the Barts BioResource. Instead, your sample(s) including tissue will be treated like a gift with the aim of enabling research into the identification, treatment and prevention of diseases of the heart and circulation. Normally, we will take the sample(s) whilst you are attending a planned surgery, medical procedure or outpatient's appointment at Barts Health NHS Trust so you should not incur any additional expenses by donating a sample to the Barts BioResource. If we invite you back to the hospital in order to help us with our research your expenses will be reimbursed.

How will donating samples to the Barts Bioresource affect my hospital treatment?

Donating samples will have no effect on the treatment you are receiving.

How to contact us

If you would like more information, please visit our website at: www.bartsbioresource.org.uk

If you would like to speak to someone about the Barts Bioresource, please contact the Research Manager, telephone number 0207 882 6903.

Email address: contact.bartsbioresource@qmul.ac.uk

You may also wish to follow updates we tweet using the Twitter handle @BartsBioRes

Thank you for considering our invitation to support the Barts Bioresource