Patient Information Sheet (PIS) – Registry/Data

Information for patients for the Barts Bioresource

What is the Barts Bioresource?

The purpose of the Barts Bioresource is to allow research into diseases of the heart and circulation (cardiovascular research). 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 of the heart and circulation.

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 medical 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.

What will happen if you say yes?

The first thing you need to do is give your permission (consent) by signing the consent form (Registry/Data), which we have provided. Please keep this information leaflet to remind you what we have asked you to do.

If you agree to take part:

- Our Research Nurses/Research Assistant 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 heart and circulation, 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 unauthorized 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 may wish to contact your GP/hospital at periodic intervals for updates relating to your heart condition.

- 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 heart/vascular scan (such as MRI, ultrasound, echocardiogram), 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

- All your personal details are kept strictly confidential and are anonymised 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 maximize the benefit that can be derived from the information and samples we collect, researchers may share anonymised medical information, blood or tissue samples with researchers in other hospitals, universities or research institutes. Any medical information or samples shared in this way will be coded and will not be labeled with personal information such as your name and address.
- These organisations may be outside the UK or the European Union. Medical data and samples can be very helpful in designing new treatments and/or medications. It is possible that your medical information 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 anonymous data may be placed on publicly accessible Web sites.
- Your data will be stored for a period of up to 25 years.
- If you agree to take part, the access to your medical information will be treated confidentially and could help research to benefit those affected by diseases of the heart and circulation.

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 information for this project.

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, your details will be removed from the Registry and we will not approach you again.

If you change your mind after a long time, we cannot recall 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.

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 of the heart and circulation 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 heart 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 joining the Registry?

There are no significant risks associated with participating in the Bioresource

Who will be able to access personal details?

The Barts Bioresource is managed by experienced doctors and scientists who will ensure that your medical records are only made available to those researchers who need to have access for an approved research study. Information 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 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 joining the Barts Bioresource?

You will not receive any payment for joining the Barts Bioresource.

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

Participation 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: [under construction]

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

Thank you for considering our invitation to support the Barts Bioresource.