

PARTICIPANT INFORMATION SHEET

Title of Project: School of Cardiovascular and Metabolic Medicine & Sciences Biobank and Repository

We would like to invite you to help us with this Biobank. Before you decide whether to take part, it is important for you to understand why the research Biobank is being developed and what taking part involves. Please take time to read the following information making sure to ask us any questions you may have about the registry.

What is the purpose of the project? The School of Cardiovascular and Metabolic Medicine & Sciences (SCMMS) Biobank involves the standardised collection of tissue, blood and clinical information from individuals who might have diseases in the arteries, veins and the heart, as well as from healthy controls. The great advantage of the Biobank is that it can provide researchers with complete sets of clinical data, tissue, and blood samples to answer important clinical questions, helping to facilitate the integration and analysis of clinical and biological data. In turn, by having a Biobank of samples/clinical data available, individual participants are exempt from the burden and the stress of being asked to donate samples on more than one occasion.

Why Have I been asked? The doctors looking after you have identified that you are being seen by one of our physicians or that you are due to have a procedure (i.e. surgery) during which a piece of body tissue is removed. We would like your permission to use this tissue and/or to take a blood sample for research purposes.

What will I have to do if I agree to take part in the project? We are asking for your consent to use tissue that must be removed for treatment purposes, and we, the Biobank, would like your permission to retain some of the tissue. No change will be made to your usual medical care whether you take part in this Biobank or decide not to. Should you agree to participate, we will also take a blood sample (6-8 teaspoons) that will be kept along with your tissue. Blood will be taken by an appropriately trained medical professional at the same time of your routine blood collection or at a later date if you opt to do so. A urine sample may also be requested and kept with your tissue.

Relevant sections of your medical notes and data collected may be looked at by responsible individuals from the SCMMS research team and regulatory authorities or from the NHS Trust where it is relevant to your taking part in research. You will need to give permission for these individuals to have access to your records.

At some point in the future, participants may be re-contacted by the Biobank team regarding this Biobank data or follow up samples' collection. You may be contacted by post/e-mail/telephone by a member of the Biobank team, although giving such additional help would be entirely optional.

What will happen to the sample I donate? If you agree to take part, the samples that are collected will then be taken to a Human Tissue Authority regulated laboratory within the SCMMS. The blood will be separated into serum and plasma. DNA may also be extracted from blood or tissue samples. All the processed samples will be stored in our research facilities. A number will be given to your sample in order to correlate it with the relevant medical details. However, no identifying features (i.e., your name, date of birth) will be shown on the specimens. Your DNA sample may be used for future genetic research but not for research that involves reproductive cloning.

Not all cause-effect studies are possible in humans and therefore, some of your samples may be analysed using our animal models of specific diseases. Alternatives to research involving animals will be used where possible. All animal work will be performed in accordance with the Animal (Scientific Procedures) Act 1986 (ASPA) and amendment regulations 2012.

What are the possible benefits of taking part? There will be no direct benefit to you at this stage. However, we anticipate that information from studies on the Biobank material will help us have a better understanding on the mechanisms of cardiovascular disease, improve the prognosis by diagnosing early and implement safe treatment.

Will my taking part in this study be kept confidential? Yes. Your identity and details will always be maintained as strictly confidential. We will not be able to supply you with your own individual results from this research. There are no implications to you personally from the results of these analyses. No results from any individual participating in the registry can be made available to any third party unless there is a clinically significant finding. In this case, information will only be shared with your GP. Published results from these studies will not mention you by name and your individual results will not be traceable through any published material.

What is happening with my personal data? We will need to use information from you for the Biobank. This information will include your name, NHS number, hospital number and contact details. We will use this information to check your records to make sure the research is being done properly. When you agree to take part in this Biobank, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure.

You can find out more about how we use your information at www.hra.nhs.uk/information-about-patients/. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research. *This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance. 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.*

Do I have to take part? No. Your participation is completely voluntary. You can refuse to participate or stop being part of the project at any time without stating a reason. Your decision not to take part or to withdraw will in no way affect the medical care you receive.

What happens if I decide to withdraw from the study? Should you change your mind about participation in this Biobank, you can let us know your wishes. Although you will not be further contacted, your samples and all data collected from those samples will be kept. You are free to withdraw at any time and your decision will be respected and will not affect your current or future care in any way.

Contact for further information. You are welcome to show this sheet to your family and friends if you would like to discuss any aspect of the Biobank and we would be pleased to answer any questions that you may have. Please feel free to contact a member of the School of Cardiovascular Medicine & Sciences Biobank team by e-mail to cardiovascular.biobank@kcl.ac.uk if you wish further information or to discuss the project.

Please retain a copy of the information sheet and one copy of the signed consent from.

Thank you very much for your help.

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the NRES London-Fulham Committee