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INFORMATION SHEET FOR CAMBRIDGE BIORESOURCE VOLUNTEERS

“Time course and determinants of arterial stiffening”

You are being invited to take part in a research study. Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with relatives, friends and your GP if you wish. Please ask us if there is anything that is not clear or if you would like more information.

Why are we doing this study?

As we get older, our arteries stiffen. This leads to an increase in blood pressure and places us at greater risk of strokes and heart attacks. We are not sure how quickly our arteries stiffen, or whether they stiffen more quickly in older, than in younger people. Also, the reasons our arteries stiffen with age are not well understood. We now have the means to assess arterial stiffness and the aim of this study is to measure how quickly arteries stiffen over time, and why they stiffen.

Why have I been asked to participate?

You have been asked to participate in this study based on your initial recruitment into the Cambridge BioResource and on the basis of your genetic make-up determined from your first donated blood/saliva sample.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be asked to sign a consent form. However, you are free to withdraw from the study at any time without giving a reason.

What do I have to do?

If you agree to take part, then you will be invited to attend a single visit at the Vascular Research Clinic in the Clinical Pharmacology Unit at Addenbrooke's Hospital. Your visit will last ~90 minutes in which you will be asked to complete a detailed medical history questionnaire. Then, after lying down for 15 min, you will have your blood pressure taken, just like at your GP and a small, pencil-like probe will be placed on the artery at your wrist, neck and upper leg to calculate how stiff your arteries are. We will place some stickers on your chest and neck and ask you to breathe some air and inert gas in and out of a tube to measure your cardiac output and lung function, and we will use ultrasound to scan your heart, the artery in your neck and your heel bone (this last reading is to assess bone mineral density). We will then measure an ECG to record small changes in your heart rate, and take a photograph of your eye to look at the small blood vessels there. None of these measurements are painful, and do not involve any needles. We will then ask you to give a blood sample of approximately 50mls (3 tablespoons of blood). This sample is used to measure various levels of naturally occurring substances in the blood, (eg. cholesterol, glucose). Some blood will also be taken and stored for future analyses, which will examine the genes which

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are known, or likely to be important in determining how stiff or elastic your arteries are. We will also ask you to collect your urine in a container for 24 hours, and to wear a small blood pressure monitor over the same period. We may also ask if you would be willing to attend a further visit, in which some more detailed measurements will be performed, but we will provide you with further information about these measurements at a later date.

Will there be any side-effects?

Taking blood may lead to minor discomfort, but only experienced people will take blood samples.

Are there any risks involved in taking part?

Apart from the blood sample, all of the measurements are non-invasive and we don't foresee any risks involved.

Are there any possible benefits to taking part?

You will have a detailed assessment of your blood pressure and other cardiovascular risk factors (eg cholesterol levels) and we will be happy to make your results available to you, if you wish.

Will my taking part in this study be confidential?

If you consent to take part in this research, you will consent to the collection, processing, disclosure and transfer of your personal data for medical research purposes only. We will follow ethical and legal practice and all information about you will be handled in confidence.

Will my GP be informed?

The doctor in charge of the study will inform your GP of your participation in the study.

What will happen to the study results?

The results of the study may be published a few months after completing the study. You will not be identified in any report or publication.

What happens if something goes wrong?

The doctors involved in the study, and the Clinical Pharmacology Unit have suitable indemnity insurance if you are harmed due to someone's negligence. However, there are no special compensation arrangements for non-negligent harm. Regardless of this, if you wish to complain about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms will be available to you.

Who is organising this study?

This study is being organised by the Clinical Pharmacology Unit of the University of Cambridge and the investigator in charge is Dr Carmel McEniery.

Who has reviewed this study?

The Cambridge Research Ethics Committee has reviewed this study and given it a favourable opinion.

Contacts for research-related enquiries:

If you require more information about the study, then please direct enquiries to **Mrs Jane Smith on Tel 01223 586852**. Alternatively, you may wish to speak to the Principal Investigator:-

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Thank you for reading this information sheet.

Remember - You are under no obligation to participate in this study. If you wish to leave the study at any point you may do so for any reason. Please take as much time to read this leaflet as require; do not feel that you have to make a decision quickly. Researchers will be available to answer any questions you may have. All the data collected will be confidential and is only for the purposes of research.