MRC Epidemiology Unit

UNIVERSITY OF CAMBRIDGE

Participant Information Sheet

Biological sample collection for the Development, Evaluation and Monitoring of Biomarkers (DEMOB study)

Summary

- 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 the time to read the following information carefully. Discuss it with friends and relatives if you wish.
- You are free to decide whether or not to take part in this research. If you choose not to take part, this will not affect the care you will get or receive.
- Please do ask us if there is anything that is not clear or if you would like more information.
- We would like you to provide blood and/or urine samples. If you agree, we will ask you to visit the MRC Epidemiology Unit to see a field team member. We will ask you for a venous and/or finger prick blood sample and/or saliva sample. If you are providing a urine sample, we will give you the necessary equipment for you to collect, store and return the sample to the Unit.
- The information and results collected will be used for research purposes only and will not be used for clinical purposes or shared with you.
- Thank you for considering supporting our research.

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How to contact us

If you have any questions about this study, please contact the study team:
Email: DEMOBstudy@mrc-epid.cam.ac.uk

1 Why we are doing this study

What are we studying?

The Nutritional Biomarker Laboratory (NBL), MRC Epidemiology Unit, develops and applies novel nutritional and related biomarker assays for use in human population research studies. On occasion, in the development of new methods or assays, we require blood or other biological samples to develop and test analytical methods. We are interested in collecting blood, saliva and/or urine samples – the study team will inform you about exactly which samples we would like to collect.

2 Why am I being asked to take part?

We would like to recruit participants who are over the age of 18 and who live or work within close proximity to our testing site (CB2 post code area).

3 What will happen to me if I take part?

If you agree to help us with this research, we will email you a link to a consent form that you must complete to take part in the study.

We will then invite you by email to come into a secure area in the MRC Epidemiology Unit to meet a field team member and have a venous sample (up to 50 mL; ~ 8 teaspoons) and/or a finger prick sample taken. We may ask you to fast overnight prior to providing the blood sample. We may ask for a saliva sample. We may provide you with equipment to collect a urine sample. This may be done in the Unit, or you can take the equipment home and later return the sample to the Unit.

4 Possible benefits and disadvantages of taking

What are the possible benefits of taking part?

You will be helping and contributing to important research in relation to nutrition and health.

What are the possible disadvantages and risks of taking part?

You may develop minor bruising from the blood collection.

5 More information about taking part

Do I have to take part?

No, it is up to you to decide whether or not to take part in this study. You are free to withdraw at any time, without giving a reason. This would not affect the standard or type of care you receive. The samples you provide are anonymised; if you did withdraw it would not be possible to remove your samples from the study. As part of asking for your consent, we will also ask if you would like to be potentially re-contacted for future research. This is optional and does affect your participation.

Will I receive any payment for taking part?

Unfortunately, it will not be possible to provide payment for taking part.

What if there is a problem?

If you have a concern about any aspect of this study you should ask to speak to the research team who will do their best to answer your questions at:
DEMOBstudy@mrc-epid.cam.ac.uk

If you remain unhappy and wish to complain formally, the normal University of Cambridge complaints process is available to you through the University of Cambridge Clinical School Secretary: telephone: 01223 333543 or email: SchoolSec@medschl.cam.ac.uk.

What will happen to information about me collected during the study?

Information we collect during the course of the research will be kept strictly confidential. Any data collected about you will have your name and address removed so that you cannot be recognised from it and it will not be used or made available for any purpose other than for research. Your samples may be stored and used in the future by ourselves or collaborators and this might include industrial or overseas collaborators. The codes used for your blood samples will not be connected to your individual identity in any way and therefore your samples are anonymous from the point of collection.

Cambridge University is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this. Cambridge University will keep identifiable information about you for 20 years after the study has finished.

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 level of personally-identifiable information as possible. You can find out more about how we use your information at:

https://www.medschl.cam.ac.uk/research/privacy-notice-how-we-use-your-research-data/

What will happen to the results of the study?

The study results will help us develop and evaluate new methods and monitor the performance of both current and future assays. Summary data obtained from the samples that you and others provide may be included in reports and scientific publications.

Who is organising and funding the study?

This study is organised by the MRC Epidemiology Unit, part of the University of Cambridge. The funder is the NIHR and Medical Research Council (MRC).

Who has reviewed the study?

This study has been reviewed internally at MRC Epidemiology Unit and by the Research Ethics Committee to protect your safety, rights, wellbeing and dignity. The study has been given a favourable opinion by Human Biology Research Ethics Committee, University of Cambridge.

6 Contact for further information

If you have any questions regarding the study or how you might be involved:
Email: DEMOBstudy@mrc-epid.cam.ac.uk

Principal Investigator

Dr Kerry Jones
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MRC Epidemiology Unit, University of Cambridge

Thank you for taking the time to consider participating in this study.