

PLEASE notify us of any future CHANGE OF ADDRESS, either by completing the enclosed 'Contact Details Update' form or by contacting us via the

EPIcure Website on:

www.epicure.ac.uk/about-us/contact-us

EPIcure Office
Institute for Women's Health
Medical School Building
University College London
74 Huntley Street
London WC1E 6AU



Tel: 0203 108 2045



epicure@ucl.ac.uk



www.epicure.ac.uk



EPIcurestudy



EPIcurestudy

EPIcure is funded by



EPIcure is also a friend of



EPIcure@19

Population based studies of survival and later health status after extremely premature birth

Study Information Leaflet

Thank you for your help with the EPIcure study

This leaflet explains what is involved in taking part



We are now ready to start the next EPIcure study, -EPIcure@19- and we would like to invite you to come to London to find out more about the study and decide whether or not you wish to take part.

Because EPIcure is such a unique study the results of the assessment will be really useful in understanding the effects that being born prematurely has had on your development. The results mean more if we have information on as many of you as we can so we do hope you can help us with this exciting project.

This leaflet explains what we would like to do so that you have the opportunity to think about whether or not you would like to take part in this study.

If after reading this leaflet, you agree to travel to London to see us, which you can tell us by completing and returning the enclosed reply slip, we will be in touch again later with details of your travel date and arrangements. This will be after January 2014.

Alternative arrangements are available for those who do not wish to travel but are interested in finding out more about the study and in how to participate. Please see page 6 of this leaflet.

If you agree to come to University College Hospital, a doctor or nurse from the EPIcure study team will welcome you and spend time with you to explain in greater detail what is involved in taking part in this study. This will also offer you a chance to ask any question you may have at the time about the study.

If in the meantime you or any member of your family have any queries at all about the EPIcure@19 study please do not hesitate to contact us. Our full contact details are at the back of this leaflet and we look forward to hearing from you at any time.



Additional information (continued)

Study review: The EPIcure study has been reviewed and approved by independent professionals from the Medical Research Council who provide the funding for the study, by the Research and Development office at University College London and by the NRES Hampshire-A Research and Ethics Committee in Southampton.

Harm: We do not anticipate any harm will come to you as a result of taking part in this research. Should you have any comments or complaints about your participation in this research study please contact the chief investigator Professor Neil Marlow in writing using the email address epicure@ucl.ac.uk. Please be assured that all complaints will be dealt with in a timely and efficient manner.

Study closure: At the end of the study all documentation and electronic information will be stored securely according to UCL Data Protection Regulations and MRC requirements for the storage of medical research documents. This means the documents and electronic data may be securely stored for up to 20 years after the end of the study under conditions of strict access control.

WHAT YOU NEED TO DO NOW

- Should you have any further questions after you finished reading this leaflet, please do not hesitate to contact us using the contact details provided at the back of this leaflet;
- Complete the reply slip to let us know if you wish to learn more about the study and what arrangements we need to make for that;
- Complete and update the Contact Details Update form;
- Please place both documents in the FREEPOST addressed envelope provided (no stamp required).

**THANK YOU VERY MUCH AND WE LOOK FORWARD TO HEARING
BACK FROM YOU**

Accommodation and other arrangements

We will make all necessary arrangements for your travel and will book accommodation for one night at a local hotel within easy travelling distance of the Hospital. If you choose to have someone accompany you we will make arrangements for them as well. Please tell us of any special needs/requirements in the reply slip enclosed. All meals and relevant expenses for both you and your travel companion will be covered by us. We will also give you £100 as a thank you for taking part in this study.

If you prefer not to travel but are interested in finding out more about the study and are considering taking part, please let us know by ticking the appropriate box on the reply slip. We will then be in touch and with your permission arrange for a doctor or nurse from the **EPIcure** team to come to your home and talk to you about the study. If you agree to take part the doctor/nurse will be able to carry out a limited number of tests on the day with your permission.



Additional Information

Confidentiality: All information collected during the study will be kept strictly confidential and only disclosed to you upon request. If we find something unexpected it will be discussed with you and we will also contact your parents/guardians, if you wish. The data used in analysis and in all publications is completely anonymised and cannot be traced to individuals.

Samples: All biological samples collected will be anonymised and stored at the University College London (UCL) Biobank, a secure facility especially set up to deal with human samples for research purposes. The samples will not be used for studies other than EPIcure unless the appropriate consents are obtained.

What is involved in taking part in the study ?

The assessment will take place over the course of two days with all accommodation and meals provided. We would like to do a medical assessment and a psychological assessment and then invite you to have an MRI scan and a blood test, as described below. You may not want to do one or more parts of the assessment. You don't have to decide until the time of the assessment and we will always ask you first. You can also ask to stop a test at any time.



The medical assessment

We will measure your height, weight and head circumference first. We will also take an image of the back of your eye. We then have three areas we would like to know about:

How well your lungs work: This involves asking our nurse and doctor to carry out similar tests of how the lungs work as we did when you were 11 years, using a machine called a 'spirometer'. This measures how fast air moves in and out of the chest by simply blowing into the spirometer. With your permission we would then ask you to take two puffs from an inhaler containing a drug called Ventolin (salbutamol) to see if your measurements are different when the drug has opened up your airways. We then would like to ask you to inhale some saline (water and salt solution). This will make you produce some mucus that we would like to collect for analysis.

How flexible your blood vessels are: this involves using ultrasound (high frequency sound waves you can't hear) to study blood flow at the wrist and neck. This is not painful or uncomfortable and involves placing an ultrasound probe against the skin of your wrist, neck and upper leg. As a second test we would ask you to wear a small sticky patch, like a plaster, on your upper arm over the assessment period. Wearing it is not uncomfortable and it uses novel electronics to monitor your blood pressure over a whole day without disturbing you, what ever you are doing.

Your sensitivity to touch and temperature: using small plastic hairs, warmth and cold we can work out how sensitive you are to small changes in each of these factors.

Thinking and problem solving

The tests in this section are about your thinking and ability to solve simple problems using tests similar to those we have used

before when you were 11 years old. Many of the tests are now in electronic form so they can be done on a computer. The EPIcure researchers will also interview you about your life since leaving school and what your thoughts about the future are. He/she will also ask if you could complete some questionnaires about your feelings.

The Magnetic Resonance Imaging (MRI) scan

MRI is used routinely in medicine now to obtain detailed images of the body using strong magnets and it is a safe procedure without known risk. We want to use MRI to look at your brain and the blood vessels in your neck. This involves you lying on a couch while your head and neck are in the scanner. The scanner makes some loud noises but you feel nothing while it is working, it is just that you have to lie still during the procedure so that the images we obtain remain sharp. We often ask people to bring a video or some music with them to watch or listen to while the scanner is working as each scan lasts a little over 1 hour. We would like to do two scans on different days. During one part we will ask you to solve a simple problem on a TV screen while the scanner is working. During the test you can talk to one of the EPIcure team at any time and even ask for the test to be stopped.

If you are unsure about having the scan we can arrange a visit to the scanner so you can try it out without the scanner working and you can ask any questions you may have. If you agree to have the scan we can give you a picture of your brain if you want one after completion of the procedure.



Blood and urine samples

Because you are now an adult it would be really helpful if we could have a blood and a urine sample to study factors that might predict the risk of later disease. These will not predict your individual risk but we can compare the levels of a range of chemicals with people who were not born early to see if there are differences. We would also like to carry out some studies of your genetic make up. We started to do this at 11 years and need to do some more work on the genetic factors that have contributed to your development.

Your overnight stay

You should be free from 6:00 pm on the first day so you can enjoy an evening in London. We will only ask you to keep the blood pressure monitor on and we will give you a small piece of equipment and instruct you on how to wear it when you are back in your hotel room so that we can measure your breathing while you sleep.

Analysing the results

All the results of our tests are treated in strictest confidence. We never release any of the information we hold on you to anyone other than yourself unless you specifically ask us to. When we publish the results it is not possible to identify individuals from our publications. In the unlikely event that there is an unexpected but important finding on the scan or on the blood or urine test, we will contact you to explain what we found and what needs to be done.

Where will we run the study?

Because some of the information we would like to collect involves using delicate equipment, the testing will take place at University College Hospital, which is located in central London, close to Euston rail station and with excellent public transport connections.

Some parts of the assessment will take place in the Hospital Clinical Research Facility, which is a modern, well equipped and friendly place and where you will be made to feel very welcome and at ease.



University College Hospital