

INFORMATION SHEET I

You are being invited to take part in the last phase of the West of Scotland Twenty-07 Study, which you may remember began in 1987. Before you decide, 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 others if you wish. Please do not hesitate to ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the West of Scotland Twenty-07 Study?

The Twenty-07 Study is a community survey which began in 1987 and examines the relative importance of a number of factors for changes in people's health over time. These factors include where you live, whether you have a job and if so what job you do, whether you live alone or with other people, and personal factors such as your diet, exercise, smoking and alcohol consumption.

Why me?

In 1987 we selected people who were then aged 15, 35 and 55 based on where they lived. You were one of those people and we have interviewed you on a number of occasions over the years since then. It is really important that we talk to the same people again so that we can understand how changes in people's lives affect their health. So we are contacting you now to ask for your help again with this final interview.

What will be involved?

You will be contacted by a nurse to arrange a convenient time for them to visit you. Once an interview time has been arranged the nurse will send you two booklets to complete before the interview. This should take no more than 15 minutes.

The interview includes three main parts.

First, the nurse will ask you questions about your health, and your living and working circumstances now and over the last few years. The information will be recorded on a laptop computer and we expect this will take about an hour to an hour and a half, although it will vary according to your particular circumstances.

Secondly, the nurse would also like to complete some physical measures with you. These will be your pulse, blood pressure, height, weight, waist and hip circumference, lung function, reaction time (to assess the speed of your reactions) and the AH4 a test of your reasoning skills. In addition there will be three new measures this time, which we hope you will agree to do: your sitting height; your internal body fat by directing a very mild electric impulse through electrodes attached to your hand and foot, which is entirely safe and will not hurt at all (bioimpedance); and your hand grip strength, which gives an indication of your upper body strength.

We expect the physical measures to take about three-quarters of an hour to complete.



Finally, if you agree, in this final phase of the Study we would also like to take blood samples which will give us biological markers of your health. We would like to take 39ml of blood, which is about 7.5 teaspoons. You can take part in the study without giving a blood sample if you wish. We will tell you a little more about this below.

Before the nurse begins the interview, she will ask you to sign a consent form agreeing to take part in the study. During the interview, you can choose not to answer any questions, refuse any physical measure you do not want taken or stop the study at any time. We will also ask you to sign a consent form before we take the blood samples and again you can refuse any measure at any time. If you choose to do the physical measures and give a blood sample, after we have analysed your data, we will send your results back to you and your GP, if you wish.

Why are we asking for a blood sample and what will happen to it?

The blood sample is required to give us more detailed information about the general health of the people taking part in the West of Scotland Twenty-07 Study. However, before you agree to donate a blood sample, it is important that you understand what will happen to it now and how it may be used in research in future.

- First, a portion of the sample will be used right away for general health screening. This will involve testing the sample for levels of lipids or fats (e.g. cholesterol) in the blood and other common markers of health (e.g. blood cell count, liver and kidney function, markers for future heart problems, diabetes, and blood cell ageing). It will not involve testing for blood borne viruses, HIV or Hepatitis B or C. We realise that the results of the health screening may be of importance to you and, at your request, we will send you a copy of selected results and, with your permission, a copy to your GP together with the results of some of the physical tests. This is covered specifically in the consent form that you will be asked to sign.
- Second, we wish to carry out a genetic analysis because research has shown that our genetic make up may influence our risk of developing certain illnesses. To do this we will extract some DNA (the substance that makes up your genes) from a portion of your blood sample. The DNA sample will be assigned a unique code so that your identity will be protected at all times then stored by the MRC for use in future research into the genetic basis for disease and the response to treatment. It will then be transferred to the MRC Twenty-07 Study Tissue Bank where it will be available for use in future research. A separate Information Sheet (2) and Consent Form (3) to cover this has been provided. Such research will take place in the future and hence we cannot give you any genetic information now. We will not give you genetic information in the future because we cannot say now what bearing it might have on your health.
- Third, the remaining portion of the blood we collect will be transferred to the MRC Twenty-07 Study Tissue Bank where it will be available for use in future research. A separate Information Sheet (2) and Consent Form (3) to cover this has been provided.

What happens now?

A qualified nurse who is one of our interviewing team will contact you to arrange a suitable time and place to conduct the interview. This will usually be your home unless you would prefer the interview to be conducted somewhere else.

What do I have to do?

It would be helpful if you do not give a blood donation in the week before our visit and we would suggest that you don't do any heavy physical activity or eat a heavy meal in the two hours before the nurse is due to arrive.

What are the possible disadvantages and risks of taking part?

During the collection of blood it is possible that you may feel faint or have some slight bruising. However, only trained and experienced nurses will conduct the interviews and they will know what to do in the rare event that this happens.

What are the possible benefits of taking part?

The information that you provide as part of the Twenty-07 Study helps us to understand why some people are healthy and not others. This information has been published in scientific papers and presented to health care professionals and the Scottish Executive to help them decide how to improve the health of people living in Scotland.

More personally, if you wish, we will give you the results of the physical measures and blood test and, with your permission, these can also be sent to your GP.

Will my taking part in this study be kept confidential?

All information which is collected about you during the course of the research will be kept strictly confidential. You will be identified by a unique number and any information which could identify you will be removed so that you cannot be recognised from it. The unique number that connects you to your data will be kept securely and separately by the MRC. No information that is published from the Study will identify the individuals who took part.

What happens after the interview?

Within two months of your interview, with your permission, we will provide you and your GP with some simple physical measures we have taken during the interview with you. These will be your height, weight, body mass index (calculated from your height and weight to see if you are over or under weight), body fat composition and some blood results – total lipids (which tell the doctor about your cholesterol level) and HbA1c (which is an indicator of glucose tolerance and a marker for diabetes). It is possible that these results may be used by your GP to help monitor your health and your GP may wish to include these results in any future report about you.

During the interview we will ask you if we can continue to follow up on your health through the Scottish Morbidity Records held on you by the Information Services Division (ISD) of NHS Scotland. We would like to ask for your consent for us to send your name, address and date of birth to ISD so that they can access your coded hospital records. These records hold data on you about medical diagnoses and in-

patient and out-patient visits to hospital. They are linked with other information about cancer registration and mortality but do not link to GP records. By linking this information with the interview data, we can look at how people's lifestyles and circumstances can have an impact on their future health. This information is confidential and will be used for research only.

We will also ask your permission to contact you again in the future to send you information about the findings of the study as they become available, and perhaps to ask you to take part in more detailed studies to follow up on findings from this interview. We are not asking you to take part in a future study now but, with your permission, we may want to contact you about one in the future.

What will happen to the results of the Twenty-07 Study?

The main study will take place between September 2007 and Summer 2008. Once all the interviews have been completed, we will carry out analyses of the data collected. The results will be published in scientific journals, practitioner and policy papers, and on our website. We will also send summaries of the results to you from time to time. Most of these analyses will be undertaken by MRC staff in our Glasgow offices. However, some times we collaborate with experts in other universities to develop the most effective understandings of the data.

More generally, the data we gather from you and other study participants are very important and would be very useful to other researchers. We will therefore ask you during the interview, if you are happy for us to deposit your anonymised data in a data archive so that other trusted researchers can apply to analyse them. This will increase the understanding of health that can be gained from the data you have provided. We will only share your data if you agree.

Who are we?

We are a group of researchers from the MRC Social and Public Health Sciences Unit based in Glasgow (www.sphsu.mrc.ac.uk). The MRC (Medical Research Council) was established in 1913 and aims to improve health by promoting research into areas of medical and related science. It is funded mainly by the government but is independent in its choice of which research to support.

Who has reviewed the Study?

The Tayside Committee on Medical Research Ethics, which has responsibility for scrutinising proposals for medical research on humans, has examined this proposal and has raised no objections from the point of view of medical ethics.

Thank you for taking the time to read this information. We hope you will be able to assist us with this study. Should you require any further information or have any concerns, please contact Catherine Ferrell, Survey Manager on 0141 357 3949 or our **FREEPHONE 0800 389 2129** or email: survadmin@sphsu.mrc.ac.uk.

Thank you for agreeing to take part in the West of Scotland Twenty-07 Study.

You will be given a copy of both information sheets and the three signed consent forms to keep.