

THE MILLION WOMEN STUDY

CONSENT AND PARTICIPANT INFORMATION: SUMMARY

Million Women Study recruitment, 1996-2001: all women in the study

Women were recruited into the study through a postal questionnaire sent with their invitation to NHS breast screening and returned when they attended for screening. The questionnaire gave information about the study, and asked for signed consent for follow-up, including through women's medical records. The recruitment questionnaire can be viewed on the study website.

This is the wording describing the study, on the front of the questionnaire:

We need one million women to help us in research that will benefit women all over the world.

Would you become one of these special women?

More and more women are taking hormone replacement therapy (HRT) so it is vital that we find out as much as possible about its benefits and any possible side effects. We have a unique opportunity through the NHS Breast Screening programme to learn about the way different types of HRT and other lifestyle factors affect a woman's health, particularly her breasts. Britain is the only country in the world that can carry out this study because it is the only one with the combination of a large population and a comprehensive national breast screening programme.

The NHS Breast Screening programme, the Imperial Cancer Research Fund and the Medical Research Council have joined together to organise The Million Women Study. If one million women answer this questionnaire over the next 3 years we could have some of the answers to our most important questions about HRT within 5 years or so.

We would be very grateful if you could set aside some time to answer these questions. It should not take more than 10-15 minutes. You do not have to answer this questionnaire and if you decide not to you will still have your screening done in the normal way.

Please answer every question and do not leave blanks as all the information that you give us is very useful. If you are not sure about exact dates or ages an approximate answer is better than none. If you have any questions you can ring us on Freephone 0800 262 872.

Even if you are not taking HRT it is just as important that you fill in the questionnaire.

Please bring this questionnaire to your breast screening appointment.

This is the wording of the consent form, on the back of the questionnaire:

So that we can find out about your health in the future we may need to contact you again or look at your screening or medical records. We would be grateful if you gave us permission to contact you again or to use information from those records. **We guarantee that all information obtained will be treated with absolute confidentiality and used for medical research only.** Of course, you do not have to give permission. Your response to this request will not affect your screening or the treatment you receive in any way.

If you give permission, please sign here and print your name, address and other details in the section below.

Please print in BLOCK CAPITALS as clearly as possible.

[signature, date]

[surname, given name(s), house number, street, district, town, county, postcode]

[surname at birth, town of birth]

[NHS number, breast screening number]

THANK YOU VERY MUCH FOR YOUR HELP.

Million Women Study: Disease Susceptibility in Women (collection of blood samples for genetic and biochemical tests): 2006 onwards, selected women in the study

Since 2006, some 50,000 women in the Million Women Study have provided a blood sample for genetic and biochemical tests. Women providing a blood sample signed a consent form agreeing that we could perform genetic and biochemical tests as necessary for our research; that they would not receive individual results from these research tests; and that subject to ethical approvals we might use their blood samples for future studies which could not be anticipated at the time. Women were informed about the Disease Susceptibility Study through a Participant Information Leaflet (attached below).

This is the wording of the consent form:

We are asking you to sign this form if you agree to join the part of the Million Women Study looking at disease susceptibility in women. This involves providing a blood sample.

We are asking for permission to store your blood sample and to use it for a variety of tests now and in the future. Your blood sample may also be useful to us for future studies related to the Disease Susceptibility Study and we are asking in addition for your permission to use the sample for such studies, all of which will be approved by the appropriate ethical body. If you have any questions or comments about the study, you can ring us on freephone 0800 262 872.

If you are willing to take part in the Disease Susceptibility Study, please read the following statements and sign below:

- 1. I confirm that I have read and understand the information sheet and consent form for the above study.*
- 2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.*
- 3. I give permission for my blood sample to be stored by the Million Women Study and used for whichever genetic or other tests are necessary now and in the future for the Disease Susceptibility Study.*
- 4. I confirm that I give permission for the Million Women Study to obtain relevant information from my GP, hospital or other medical records.*
- 5. I understand that my personal information will be treated with absolute confidentiality and used by the Million Women Study for research purposes only. Anonymised information from the study may be looked at, for audit purposes, by authorised individuals from the research sponsor (University of Oxford).*
- 6. I agree to take part in the Disease Susceptibility Study.*

Signed : Date : Name :

If you also agree to allow us to use your blood sample for future related studies, please sign below:

- 7. I give permission for the Million Women Study to use my blood sample for other related studies in the future, subject to approval of such studies by the appropriate ethical body.*

Signed : Date : Name :

Please return ONE signed copy of this consent form, with your blood sample, in the prepaid envelope provided to: The Million Women Study Co-ordinating Centre, CEU, University of Oxford, Richard Doll Building, Roosevelt Drive, Oxford OX3 7LF. The other copy is for you to keep.

Thank you.

Professor Valerie Beral

THE MILLION WOMEN STUDY

A national study of women's health

The Million Women Study Co-ordinating Centre
CEU, Richard Doll Building
Roosevelt Drive
Oxford OX3 7LF

INFORMATION SHEET

THE MILLION WOMEN STUDY: DISEASE SUSCEPTIBILITY IN WOMEN

Thank you for completing the Million Women Study questionnaire sent to you recently. Our records show that you have indicated you might be willing to provide a blood sample for the study.

The Million Women Study is looking at the effects of many different factors (including, but not only, hormone replacement therapy) on the risk of breast cancer and other diseases. An important area of our research is looking at how other factors such as a woman's genetic make-up and her hormone levels may affect her health. The Million Women Study offers a unique opportunity to study the effects of these risk factors in depth because it is so large (nearly 1.4 million women are taking part) and because women have already given us such detailed information on their use of medication and on other lifestyle factors which may also affect disease risk. There is more information about the study on the back of this sheet.

In order to test for genetic and biochemical factors, we need to collect blood samples. We are asking some women who have returned a Million Women Study follow-up questionnaire if they will take part in the Disease Susceptibility part of the study. This involves providing a small blood sample (12 ml; about 2 tsp). *Please note that you do not have to take part if you do not want to and that your answer to this request will not affect your future health care in any way.*

If you are willing to provide a blood sample, we ask that you read the enclosed consent form and sign both copies. Please make an appointment at your GP practice with your practice nurse or GP to have the sample taken. You will need to take the enclosed sample collection kit and paperwork to your appointment. Please send the blood sample, with the accompanying form completed by the doctor or nurse and ONE consent form back to us, in the pre-paid envelope provided. The other copy of the consent form is for you to keep. So that your blood sample reaches us without delay, please do not make your GP appointment on a Friday or Saturday, or just before a bank holiday. There is no need to fast before giving this sample.

If you do not wish to or are unable to provide a blood sample, you can use the enclosed pre-paid envelope to return the unused blood kit.

We remind you that all information and samples given to the study will be treated with absolute confidentiality and will be used for medical research only. All information will be handled in accordance with the Data Protection Act and results from the study will not identify the individual women who took part. The blood tests are for research purposes only, and you will not be sent individual results of genetic or other tests.

If you have any questions or comments about the study, please ring us on freephone 0800 262 872.

Thank you.

Professor Valerie Beral, FRCP

THE MILLION WOMEN STUDY

What is the Million Women Study?

The Million Women Study is a national survey of women aged 50 and over, looking at the factors affecting health in this age group. Over a million women across the UK have joined the study.

Who is conducting the study?

The Million Women Study is a nation-wide collaborative project. Funds for the study have been provided by Cancer Research UK, The NHS Breast Screening Programme and the Medical Research Council. Cancer Research UK and the NHS provide indemnity for the study for non-negligent and negligent harm. This means that in the unlikely event that you feel you have been harmed by taking part in the study, you can apply for compensation (using the complaints procedure described below) even if no-one has been at fault.

Why have I been asked to take part in this additional study?

You were first sent a questionnaire with your invitation to attend the NHS Breast Screening Programme several years ago, and have recently returned a follow-up questionnaire. We are asking some women who have reported having a recent illness, and others selected at random from those who have not reported such recent illnesses, to provide extra information and a blood sample for the disease susceptibility study. This will help us find out more about factors affecting a woman's risk of disease.

What is this part of the Million Women Study investigating?

The Million Women Study is investigating how hormone replacement therapy and other factors affect women's health. This part of the study will be looking in depth at how factors such as a woman's genetic make-up and her hormone levels may also affect her risk of developing disease. To measure these factors we need blood samples from women in the study.

What will happen to the samples?

The blood samples will be stored for several years and used for a variety of medical tests, now and in the future. These tests will involve looking at different genes and at levels of hormones and other blood components which may be involved in disease. Because of the need to look at a range of factors which may become important in the future, even if they do not appear important to medical researchers now, it is not possible to be specific about exactly which tests will be done. We are asking you to give us your blood sample as a gift, and hope that you will give us permission to do whichever tests are necessary for medical research in the future. If at any time you decide to withdraw from the study, your sample will be destroyed. All samples will be destroyed at the end of the study.

Will I be told the results of the tests?

Neither you nor your GP will be sent individual results of any genetic or other tests, because their meaning will not be clear at this stage. Reliable research will usually require comparisons between thousands of samples. The final results of the study will be published and will be available on the study website. If you are concerned about your susceptibility to disease, please contact your own doctor.

What else is involved?

Information from your blood sample will be put together with information from your questionnaires and with information we may request from your GP or hospital medical records, or from other NHS records such as disease registries.

Why is my participation important?

The Million Women Study aims to provide information which is relevant to all women. To do this as many women as possible, from all parts of the UK, from as many backgrounds as possible, need to take part. Your continuing participation is especially valuable as it is important to us to follow women's health over time.

Is confidentiality guaranteed?

We guarantee that all information and blood samples provided to the Million Women Study will be treated with absolute confidentiality and used for medical research only. All information will be kept in accordance with the Data Protection Act.. The Million Women Study has fulfilled the ethical requirements of the appropriate Multi-Research Ethics Committee and has been approved by all relevant Primary Care Trusts and Health Boards under the NHS Research Governance Framework.

What if I am unable to or do not wish to provide a blood sample?

Participation in any part of the Million Women Study is purely voluntary. Whether or not you take part will not affect your health care in any way and you are free to withdraw from the study at any time.

What if I have questions or complaints about the study?

If you have any questions, comments or complaints about the study, please call The Million Women Study Helpline on freephone 0800 262 872 or write to Professor Valerie Beral, at the address on the front of this sheet.