We would like to invite you to take part in our research. Before you decide we need to tell you why this research is being done and what it would involve for you. One of our team will go through the information sheet with you and answer any questions that you have. Talk to others about the study if you wish.

Part 1 tells you the purpose of this study and what will happen to you if you take part. Part 2 gives you more detailed information about the conduct of the study. Ask us if there is anything that is not clear.

**Part 1: Study Outline**

1. **What is the purpose of the study?**
   We need to learn more about young women of childbearing age, to find out how their health, lifestyle or a pregnancy may influence their health in later life.

2. **Why have I been invited?**
   You have been invited because you are young (18-40), live in the Oxfordshire area, have yet to have children and are planning to become pregnant. In this pilot phase of the study we aim to recruit 300 women. However eventually we will invite 12,000 other women like you to join this study.

3. **Do I have to take part?**
   No, it is your choice. We will give you the details and go through this information sheet with you. If you agree to take part but later change your mind, you are free to withdraw at any time without giving a reason with no implication whatsoever on your future care.

4. **What will happen to me if I take part?**
   4.1. **Considering whether to take part:** If you are interested in taking part, please contact us to discuss the study (contact details at the end of part 2). You are free to decline if you prefer.
   4.2. **Consenting to take part:** If you want to join the study you will meet a member of the research team at your usual health centre or at our recruitment centre. If you agree to take part we will ask you to sign a consent form at this appointment. You will then begin the study.
   4.3. **Starting the study:** You will have been asked not to eat or drink anything, other than water, from midnight before your appointment (which will take place in the morning) to allow for a fasting blood test. During this appointment a number of assessments will be completed and some samples will be collected (see point 6 below for further details). You will also be asked to complete a questionnaire. The appointment will take approximately 3 hours and breakfast will be provided.
   4.4. **The next stage:** If you agree, the research team may contact you in the future for further information, additional samples or other studies that might arise out of this one. If you become pregnant at any time in the next 3 years, we will ask you to contact us (you will be given the details) and for you to permit your doctor or midwife to contact us.
   4.5. **If you get pregnant:** Please contact our research team and they will give you a leaflet about the study during and after your pregnancy. If you agree, you will be asked to sign a second consent form for this part of the study. You will be offered an additional early ultrasound when you are 7 weeks pregnant. During later pregnancy there will be two extra appointments at the Maternity Unit and one extra ultrasound scan of your baby at 28 weeks.
5. Expenses and payments
To recognise the time you are committing to the study, you will receive a £20.00 gift voucher for completing the assessments at your first appointment. If necessary we will offer to reimburse travel expenses to your health centre or the recruitment centre and we can offer you a Clearblue™ pregnancy test.

6. What will I have to do?
If you take part in the study you will be asked to attend one appointment at your usual health centre or at our recruitment centre. We can separate this into two appointments should this be more convenient for you and visit 1 can take place at your own home if you prefer.

Appointments
You will be asked to do the following:

- Give written consent to be included in the study.
- Have your body size and weight measured using tape measures and scales.
- Donate samples of urine, saliva and blood (up to 40ml of blood – approx. 8 teaspoons) for storage and scientific analysis (detailed information about the blood samples are given in Part 2).
- Complete a questionnaire (whilst having breakfast provided by us).
- Remove your outer clothing and wear a gown provided by us.
- Have your blood pressure and the ‘stiffness’ of your arteries measured using a blood pressure machine and cuffs placed on your upper arms and the top of your legs.
- To measure the way the main artery works in your arm we will inflate a blood pressure arm cuff for a few minutes and measure how your artery responds to the temporary increase in pressure.
- Have an ultrasound measurement of body composition on your thigh and abdomen.
- Have a short ultrasound scan of the arteries in your neck. You will need to lie still for around 10 minutes while we take pictures using a small scanner.
- Have an ultrasound scan of your heart which involves a probe and gel on your chest.

At the end of this appointment we will give you contact details for the research team so that should you become pregnant within 3 years you can contact us if you are happy to do so. If you would like further details as to what would happen if you take part in this study during pregnancy we can give you written information.

7. What are the possible benefits, disadvantages and risks of taking part?
There is no direct benefit to you but we hope that all who take part will contribute to improving our understanding of women’s health and possibly the health of their children.

It is not felt that there are any significant disadvantages or risks of taking part. Ultrasound has no known adverse effect and has been used on healthy adults and children without problems. When inflated, the blood pressure cuffs may be associated with momentary discomfort and the blood sample collection may be uncomfortable and leave a small bruise. In the unlikely event that we identify a medical problem during the assessment, we will let you know and, with your permission, we will also inform your General Practitioner.

8. What if there is a problem?
Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information on this is given in Part 2.

9. Will my taking part in the study be kept confidential?
Yes, we will follow ethical and legal practice and all information about you will be handled in confidence. These details are included in part 2.
Part 2: Further information

10. What if relevant new information becomes available?
Sometimes during the course of a research project new information becomes available that may be relevant to those who have taken part. As this study has no immediate effect on your medical care it is felt very unlikely that this will happen, but we will inform you if any relevant information becomes known.

11. What will happen if I don’t want to carry on with the study?
You are free to withdraw your consent in the future. If you do, we can then just make use of the information we already have about you or we can ensure your samples and information that are used for future research are entirely anonymous. Alternatively we can destroy any identifiable samples or information we hold about you.

12. What if there are any problems?
It is highly unlikely that you will suffer harm by taking part. However, the University of Oxford has arrangements in place to provide for harm arising from participation in the study for which the University is the Research Sponsor. NHS indemnity operates in respect of the clinical treatment with which you are provided. If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, you should contact Dr Ingrid Granne on 01865 221021 or Ingrid.granne@obs-gyn.ox.ac.uk. You can also contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 572224 or the head of CTRG, Ms Heather House, at heather.house@admin.ox.ac.uk.

13. Unexpected findings on your scan
In the unlikely event of the tests showing any significant abnormality, your GP will be informed (if you have consented to this) and they may arrange for further investigations as necessary. However, it is important to stress that our tests are intended for research purposes only and we do not carry out tests for diagnostic purposes. Participation in this study is therefore not a substitute for a clinical appointment.

14. Will my taking part in this study be kept confidential?
The research team has a duty of confidentiality to you as a research participant. All of the information collected will be made anonymous. The information and samples that relate to you will be coded and stored with a study number so that you cannot be identified from it but it will allow us to link together the different types of information you provide. We will keep a separate register locked within the Nuffield Department of Obstetrics and Gynaecology at the University of Oxford to allow us to link the code number to your personal details so that we can contact you in future about matters directly relating to the study.

Authorised representatives from the University of Oxford may look at the anonymised results to check that the study is being performed correctly. We will keep all the data we collect for 5 years after the study has been published in line with the current University of Oxford policy.

15. What will happen to any samples I give?
The blood, urine and saliva samples will be securely stored within facilities of the Nuffield Department of Obstetrics and Gynaecology under the custodianship of Dr Ingrid Granne. Samples will only be identifiable by the study code numbers. Samples donated for research should be regarded as gifts which means that you would not own the material and would have no legal rights over them. You will not receive payment as a result of donating your blood, urine, saliva and/or tissue. The samples you have gifted will never be sold for profit.
Samples will be used for scientific measurements including analysis of substances, cellular function and genes involved in blood vessel function and cardiovascular disease, metabolic diseases, fertility and problems of pregnancy. The samples are also likely to be used for future scientific research projects that have been ethically approved, including genetic research both in the UK and overseas. The research will be carried out under the direction of the study investigators but the samples may be transferred and analysed by other research teams, and possibly by commercial research teams or researchers at other research institutions in the UK or in other countries. The University of Oxford may ask other researchers to cover the cost of transferring your samples. Other researchers will not be able to personally identify any samples. You would have no legal right to a share of any profits that may arise from the research.

In the future your samples could be transferred to an ethically approved Research Tissue Bank.

If you agree, we would like to access your healthcare records both now and in the future. This will help us to understand the results of any tests we have undertaken on the samples that you have donated to us.

16. Will any genetic tests be done?
The samples will be used for genetic research. The primary aim of the genetic tests would be to help understanding in cardiovascular diseases, metabolic diseases and problems in pregnancy. We will not be testing for genetic diseases.

17. What will happen to the results of the research work?
The results of the work will be published in scientific and medical journals. If you would like further information about the work, this would be available from the research team, whose contact details are below.

18. Who is organising and funding the research?
The study is being organised jointly by the Departments of Obstetrics and Gynaecology, Cardiovascular Medicine and Primary Care Health Sciences at the University of Oxford. The study is funded by the Oxford Biomedical Research Centre and the National Institute for Health Research School for Primary Care Research.

19. Who has reviewed the study?
All research in the NHS is looked at by an independent group of people called a Research Ethics Committee (REC) to protect your interests. This study has been reviewed and given a favourable opinion by NRES Committee South Central - Portsmouth.

20. For further information:
If you have any further questions please do not hesitate to contact our research team:

Tess Snelgar
Research Midwife
Nuffield Department of Obstetrics and Gynaecology
University of Oxford
John Radcliffe Hospital, Women’s Centre
Level 3
Headington
Oxford OX3 9DU

Telephone: 01865 572259
Mobile: 07972733856
Email: oxwatch@phc.ox.ac.uk

Thank you for taking the time to read this information sheet.