Patient Information Leaflet

We would like to invite you to take part in the Pregnancy Physiology Pattern Prediction (4P) Study.

The aim of the study is to collect vital sign measurements from 1000 women throughout pregnancy and the first two weeks after the birth in order to build up a database of values. This database will support the development of an evidence based early warning system. This will help doctors and midwives identify sick and deteriorating pregnant women and new mothers much quicker than we currently can.

This leaflet will help you to understand why the research is being done and what it would involve for you if you decide to take part.

Please read this information leaflet carefully.

The 4P research midwife will go through the leaflet with you after you have read it and answer any questions you have.

Please also speak to friends and family about taking part in the study if you wish

Part 1 of this leaflet tells you the purpose of this study and what will happen if you take part.

Part 2 gives you more detailed information about the conduct of the study.

Please ask us if anything is unclear
Part 1: The Purpose of the study and what will happen to you if you take part

What is the purpose of this study?

The two most recent investigations into the causes of health complications in pregnant women and new mothers have highlighted an urgent need to develop a system for identifying women at imminent risk of becoming seriously unwell.

The collective term for blood pressure, heart rate, temperature, blood oxygen levels and breathing rate is vital signs.

When a pregnant woman or new mother is ill, there are changes in her vital signs that can signal a worsening of the illness.

Pregnancy changes a woman’s vital signs too.

In order to identify which changes are a sign of worsening illness and which are the changes occurring naturally, we need to develop a more detailed picture of what normal vital signs are, throughout pregnancy, labour and the 2 weeks after the baby (or babies) is/are born.

The 4P study aims to collect vital signs measurements from 1000 women throughout pregnancy and the first 2 weeks after delivery.

Because some medical conditions can affect our vital signs, we will also be collecting information about your height, weight, blood results and medical history from your maternity notes. We will also record your ethnicity to help us assess whether this has an effect on your vital signs.

The data we collect will support the development of an evidence-based early warning system to identify mothers who are developing complications. This will help us treat them sooner and may ultimately save lives.

The data collected will also be used for future research.

Why have I been invited?

All pregnant women over 16 years of age and with no known serious underlying condition are being invited to take part in the study.

Do I have to take part?

It is entirely up to you whether you take part or not. You are free to say no and your decision will not affect the care you will receive in any way. We will go through this leaflet with you and answer any questions you have.

You have as much time as you need to ask questions and consider whether to take part in the study.

If you do decide to take part, our research midwife will ask you to sign a consent form.
If you have any questions about the study you can contact our research midwives. Their number is on the back of this leaflet.

**What will happen if I want to drop out of the study?**

You can decide to drop out of the study at any time, without giving a reason. The care you receive will not be affected in any way. Any data containing your identifiable details will be destroyed. Any data we have already collected will be anonymised and used in the study unless you request otherwise.

**What will happen to me if I take part?**

**During your pregnancy**

**First visit**

We will collect relevant details of your pregnancy and medical history from your maternity notes, including any blood test results, your height and weight, date of birth, medications, number of previous pregnancies and smoking history. This visit will take place at approximately 14-16 weeks of pregnancy.

We will measure your vital signs including your blood pressure, temperature, heart rate and blood oxygen levels (using a small device attached to your finger called a pulse oximeter) and your breathing rate. Firstly we will measure your heart rate by feeling your pulse on your wrist for one minute and counting the beats.

Your breathing rate will be counted by the research midwife and estimated from the pulse oximeter readings. It will also be measured using the movement sensor in a smart phone which the midwife will place on a cord loosely around your neck, resting on your chest while you sit back comfortably for a minute. We will then repeat these measurements and send them to our study data base via a tablet computer.

This first appointment will take approximately 30 minutes in total.

**Follow up visits**

Approximately every 4-6 weeks throughout your pregnancy, we would like to measure your vital signs and collect information about any newly arising medical problems from your maternity notes.

For this, we will arrange a convenient time and place (it could be in your home or here in the hospital where we have a comfortable treatment room).

We can also arrange to meet you during your routine antenatal check with your midwife.

Each appointment with the research midwife will last around 15 minutes.
After your baby is born

Home Monitoring

After your baby is born, we will collect information about your birth from your maternity notes (any vital signs measurements you had taken, type of delivery, pain relief, medications used).

After the birth of your baby we would like you to measure your own vital signs once a day at a time that suits you for 14 days.

We will contact you very soon after the birth of your baby (usually the day after) and issue you with a simple home monitoring kit comprising a tablet computer, a blood pressure cuff, a thermometer and a device for measuring your pulse, breathing rate and oxygen levels called a pulse oximeter. Your breathing rate will be estimated from the pulse oximeter readings.

The tablet computer is used to send your measurements to our study database.

![Above: 4P Home Monitoring Equipment Kit](image)

The kit is simple to use and contains clear instructions. We will show you how to use the kit when we see you towards the end of your pregnancy.

Home Visits

We would like to visit you at home twice after your baby is born to measure your vital signs. This will be around day 7 and day 14 after your baby is born.

Throughout the two weeks following the birth of your baby, our research midwives are available to help with any problems or questions you have regarding the home monitoring equipment. Our contact number is on the back of this leaflet and in the written instructions that come with your kit.

We would like to invite you to complete a usability questionnaire during this time to monitor how user-friendly the system is

Expenses and payments
You may claim back travel expenses to the Hospital if you decide to attend here for your follow up visits.

There is no payment for taking part in the study.

As a thank you for taking part in our study, we will issue you with a £20 gift voucher after we have collected the home monitoring equipment at or around 14 days after your baby has been born.

**What are the possible disadvantages or risks of taking part?**

We do not anticipate there to be any risks to taking part in the study.

The follow up visits will require approximately 15 minutes of your time every 4-6 weeks.

The home monitoring will take approximately 10 minutes a day for 14 days.

If we find a problem with your vital signs (for example; high blood pressure), we will refer you to your own GP, midwife or the maternity unit at the hospital.

**What are the possible benefits of taking part?**

Taking part in the study is unlikely to benefit you or your baby directly, however, the more frequent monitoring of your vital signs may help identify and treat problems such as high blood pressure or infection sooner.

By taking part in the study you will help us to develop a new early warning system to identify ill mothers, which may help save lives.

This completes part 1.

If the information in Part 1 has interested you and you are considering taking part, please read the additional information in Part 2 before making any decision.
PART 2: More detailed information about the conduct of the study

What will happen if I don’t want to carry on with the study?

You may withdraw from the study at any time without having to give a reason for withdrawing. Your usual care will not be affected in any way.

You will have the choice to either allow the data already collected to be used, or to have all your data removed. Any stored data that identifies you will be destroyed.

What if there is a problem?

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. Peter Watkinson on 01865-576625, email peter.watkinson@ndcn.ox.ac.uk. Or you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) Office on: 01865-572224 or the head of CTRG email: ctrg@admin.ox.ac.uk.

The normal National Health Service complaints mechanisms will still be available to you. Please see: http://www.nhs.uk/choiceintheNHS/Rightsandpledges/complaints/Pages/NHScomplaints.aspx.

You can also contact the Patient Advice and Liaison Services Office at this hospital.

- Tel: 01865 221473
  Email: PALSJR@ouh.nhs.uk

The University of Oxford, as sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm from the negligence of the University, or that of a collaborator in this research, and with that harm resulting as a direct consequence of our participation in this trial.

Will my taking part be kept confidential?

All information we collect about you during the course of the research study will be kept strictly confidential.

After you sign the consent form we issue you with a study number which we use as an identifier for study information that we collect from you and the vital signs that you send to us.

The database stores your anonymised measurements on a secure, password protected virtual server which resides behind an NHS firewall and is only accessible to the research team from within an NHS building.

The research midwives will keep a tracking sheet with your identifiable data (name, address, mobile phone number, date of birth, date of delivery) in order to keep a record of your study appointments, home monitoring kit details and details of any abnormal vital signs during the
study. This information is securely locked away in a cupboard in a locked office. Only the research midwives have access to your identifiable data. The research midwives have a duty of confidentiality towards you as research participants and will not share this information with anyone else.

The anonymised data will be viewed by a team of statisticians and biomedical engineers from the Institute of Biomedical Engineering at the University of Oxford in order to analyse the data and develop the early warning system. Direct access will be granted to authorised representatives from the Sponsor or host institution for monitoring and/or audit of the study to ensure compliance with regulations.

No individual participants will be identified when the results of the study are published.

The data that can identify you will be retained securely for 21 years after the end of the study. This is so that the data can be looked at again in the future and used in future research projects. After 10 years, the anonymous data will be disposed of securely. You have the right to check the accuracy of data held about you and to correct any errors.

**Involvement of General Practitioner (GP)**
If we notice that you have any abnormal vital signs (such as high blood pressure or a raised temperature) during the study we will ask you to inform your GP or midwife and they will monitor and/or investigate and treat this as necessary.

**What will happen to the results of the research study?**
The results will be published in scientific journals and be presented at meetings. Your name will not appear in any reports or publications. Your identity will be protected at all times. You can ask for a copy of the results by contacting the research midwife on [insert] from [insert] onwards, or by

**Who is organising and funding the research?**
The research is being carried out by the Nuffield Department of Obstetrics and Gynaecology and the Oxford Institute of Biomedical Engineering at the University of Oxford and is being funded by the Oxford Biomedical Research Centre. This is a partnership between the University of Oxford and Oxford University Hospitals NHS Trust, funded by the Department of Health’s National Institute for Health Research. The doctors involved in the research are not being paid to include you in the study and have no conflict of interest with regards to the study.
Who has reviewed the study?
Research is reviewed by an independent group of people called a Research Ethics Committee to protect your interests, safety, rights wellbeing and dignity. This study has been reviewed and given favourable opinion by NRES Committee South East Coast – Brighton and Sussex

This completes Part 2

You may keep this information leaflet for your records.
If you have any questions, please contact us as overleaf.

If you wish to take part in the study we will ask you to sign a consent form.

We will give you a signed copy to keep for your records.

Contact Details?

If you wish to receive a summary of the findings of the study please complete your contact details below:

e-mail:______________________

Home address: ___________________________________________________________________
Post code: ______________

If you have any questions, please do not hesitate to contact Jude Kemp or Clare Edwards our Research Midwives and Study Co-Ordinators:

Telephone: 07896 932882
Email: jude.kemp@obs-gyn.ox.ac.uk
        Clare.edwards@obs-gyn.ox.ac.uk
Post: NDOG, University of Oxford, Level 3, Women’s Centre, John Radcliffe Hospital
      Headley Way, Oxford, OX3 9DU