



**UNIVERSITY OF
CAMBRIDGE**
Department of Obstetrics
and Gynaecology



Pregnancy Outcome Prediction Study 2 (POPS2) participant information leaflet.

We would like to invite you to take part in a research study. Before you decide, you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. 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 or if you would like more information. Take time to decide whether or not you wish to take part.

Part 1.

Q. What is the purpose of the study?

A. We aim to obtain information (such as ultrasound scans) and samples (such as blood samples) from a large number of women during pregnancy. We also want to collect DNA from the fathers, where possible. We want to analyse these to better understand what might cause pregnancy complications and to develop improved methods for predicting which women are most likely to experience complications.

Q. Why have I been invited?

A. Because you are attending the Rosie Hospital for antenatal care, you are pregnant and you have not had any previous births.

Q. Do I have to take part?

A. No, you do not have to take part. It is up to you to decide. We will describe the study and go through this information sheet, which we will then give to you. We will then ask you to sign a consent form to show you have agreed to take part. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive.

Q. How will I be asked to participate?

A. After you have had your first scan the sonographer will know whether you are eligible for the study. She will invite you to talk to one of the research midwives who should be available after your scan is finished. However, if you have your scan and are unable to speak to the research midwife for any reason and you are interested to hear more about the study, you can call the following number (tel 01223 769262) and leave a message to arrange a specific time to come back and discuss the study.

Q. What will happen to me if I take part?

A. Participation in the study will allow the research team to collect the information and samples which are required to study what causes pregnancy complications and to develop better methods of predicting complications. Hence, visits may include obtaining information through questions, making measurements

during an ultrasound scan or obtaining blood samples. Specifically, participation in the study involves the following:

1. We will weigh you and measure your height on the day you provide consent. We will then ask you to attend the Clinical Research Facility (CRF) to have blood obtained and to make future appointments. The CRF is a 2 minute walk down a corridor from the Rosie and provides facilities for research studies.
2. Your routine mid-pregnancy scan (the detailed scan at around 20 weeks) will take place as normal. This may take place in the Rosie Hospital Ultrasound Department or in the Clinical Research Facility. Any findings from that scan will result in the same care as if you were not participating in the study. We will obtain some further measurements at the time of the scan but this will not affect your care. We will also go through a questionnaire and obtain some information (such as your general health and any medical conditions you may have) and we will obtain blood in the Clinical Research Facility. We will also obtain blood from the father of the baby if they are present and consent.
3. You will have research scans at around 28 and 36 weeks. These are scans that you would not normally have as part of routine care. You should still attend for the research scans even if your doctor or midwife books you for a clinical scan as the research scans will be obtaining additional measurements. We will let you know if these scans demonstrate any serious problem with the baby. Otherwise, we will simply use the information for the purposes of research. We will also obtain blood from you at both of these visits.
4. After your baby is born, we will obtain samples of the placenta and blood from the umbilical cord. From your perspective, this is the last point of contact with the study and there is nothing else we will be asking you to do. However, it is possible that we may contact you at some point in the future to see if you are interested in taking part in follow up studies. We may also contact your baby when they reach the age of consent. Both of these approaches would involve a separate consenting process and neither you nor your child would be under any obligation to agree.
5. Your clinical records will be accessed to obtain information on the outcome of your pregnancy (such as the baby's birth weight, whether you had complications, for example, pre-eclampsia). Your baby's clinical notes will also be accessed to determine what special care (if any) your baby required after birth. We may also access you and/or your baby's future electronic records (e.g. health or educational) to determine how pregnancy impacts on long term health.

Finally, as part of POPS2 we are also performing an additional research study where we assess whether women are at high risk of complications using a blood test plus other information and use the results to guide care. You will be given information about this at your 28 week visit and you will be asked to consent, if you are eligible, at 36 weeks. Your consent today does not in any way commit you to participating in the screening study. You will be able to decline this and it will have no effect on any aspect of your care and you will continue to have the research scans.

Q. What do I have to do?

A. To take part, you simply need to sign the consent form, attend these visits and have the scans performed and samples obtained.

Q. What are the possible disadvantages and risks of taking part?

A. There are no risks to you. Obtaining the extra blood samples may be slightly uncomfortable.

Q. What are the possible benefits of taking part?

A. The main benefit is the possibility that the extra scans might provide useful information (see part 2 of the form). We will also be happy to provide you with a picture of your baby, free of charge, at the time of your 28 and 36 week scans. This work may help other pregnant women in the future.

Q. What happens when the research study stops?

A. We plan to store your information and the samples we obtain indefinitely.

Q. What if there is a problem?

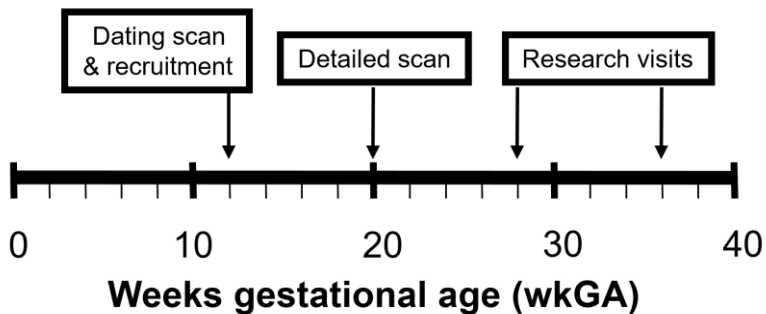
A. Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information on this is given in Part 2.

Q. Will my taking part in the study be kept confidential?

A. Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. We will use information from you, your medical records and from the research visits. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study. Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules. At the end of the study we will save some of the data for future research. We will make sure no-one can work out who you are from the reports we write. Part 2 of the form tells you more about this.

Part 2.

Study timeline:



Q. What will happen if I don't want to carry on with the study?

A. You can stop being part of the study at any time, without giving a reason. You can also request that we destroy all samples and information that we have collected and not to access your medical records. But, unless you specifically request this, we may use the information and samples collected up to that point and access your medical records. If you decide you do not wish to continue, please call us on 01223 769262. We will cancel your further research appointments but your routine clinical care will not be affected in any way.

Q. What if there is a problem?

A. If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions (telephone 01223 769262). If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. The office dealing with complaints is the Patient Advice and Liaison Service (PALS). You can write to them at Patient Advice and Liaison Service (PALS), Box 53, Cambridge University Hospitals NHS Foundation Trust, Hills Road, Cambridge, CB2 0QQ, call them on 01223 216756 or email them at pals@addenbrookes.nhs.uk. In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a

legal action for compensation against Cambridge University Hospitals NHS Foundation Trust but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

Q. How will we use information about you?

A. We will use information from you, your medical records and from the research visits. We will only use information that we need for the research study. This information will include your name, hospital number, NHS number and contact details. People will use this information to do the research. People who do not need to know who you are will not be able to see your name or contact details. Your data will be identified using a code number instead.

We will keep all information about you safe and secure. The security of storage will fulfil all regulatory requirements for the control of personal information. Paper documents with your details will be kept in locked, secure storage in an area which is access controlled (physical key and/or electronic entry). Electronic documents will be stored in password protected computers and files where access fulfils the UK regulatory requirements for the storage of personally identifiable and sensitive data. Data which allows you or your child to be identified will only be shared externally with agencies within the National Health Service or the Department for Education for the purposes of identifying long term outcome. Even then, we will simply send them your identifying details without any of the other information and all data will be transferred securely. The NHS will then provide us with information about any NHS care received by you or the baby and the Department for Education will provide us with information about your child's performance at school. We are collecting this information to try and determine how pregnancy complications and interventions relate to long term health of the mother and child.

We will not send any of your personally identifiable data outside the UK or to any commercial entities. Research data may be shared with external partners only if your personal identifying information has been removed, hence, it will be impossible for them to identify you.

Q. Can I request that my information is erased?

A. We are planning to retain the information we collect indefinitely. However, you can stop being part of the study at any time, without giving a reason. If you choose to stop taking part in the study, we would like to continue collecting information about your health and the outcome for your baby from the hospital electronic records, central NHS records and educational records for the baby. However, if you do not want this to happen, tell us and we will stop. You can also contact us at any point and request that we securely destroy all the information and samples we have collected from you.

Q. Where can I find out more about how your information is used?

A. You can find out more about how we use your information by asking one of the research team, by sending an email to pops2@addenbrookes.nhs.uk or by ringing us on 01223 769262. If you have any concerns about the use of your personal data you can contact the hospital's Data Protection Officer, Cambridge University Hospitals NHS Foundation Trust, Box 153, Hills Road, Cambridge, CB2 0QQ, or by email to gdpr.enquiries@addenbrookes.nhs.uk. The research is co-sponsored by Cambridge University and you can contact the Cambridge University Data Protection Officer at the Information Compliance Office, University of Cambridge, The Old Schools, Trinity Lane, Cambridge, CB2 1TN, telephone: 01223 764142 and email data.protection@admin.cam.ac.uk.

Q. Will my GP be involved or informed?

A. Your GP will not be required to contribute to the study. However, with your permission, we will write to your GP and let them know you are participating in the study and what is involved.

Q. What will happen to the samples I give?

A. We plan to obtain four blood samples from you at approximately 12, 20, 28 and 36 weeks of pregnancy. You will normally have routine blood samples obtained at 12 and 28 weeks and we can obtain these samples at the same time as the blood for this study. We will also obtain samples of placenta and umbilical cord (this will include tissue and some of the small volume of the baby's blood that remains in the placenta and umbilical cord following birth). The samples will be stored securely and indefinitely. The samples will be stored in locked freezers which are in turn kept in a secure locked area.

We will analyse the samples of all the women who had complications and compare them with samples from women who did not experience the complication. It is impossible for us to describe every test which we might perform on your samples as it is likely that new tests will become available in the future. It is also possible that we might identify a novel test for complications which has commercial value. The expression used in this situation is that you give your blood and other samples as a "gift". i.e. that by consenting to the study, you allow us to analyse the samples in any way we wish in the future with the aim of better understanding or predicting complicated and healthy outcomes. We may also pass samples on to collaborating researchers, and for future research studies. These collaborators may be overseas, and may also include commercial collaborators. All your personal information will have been removed and the other researchers will be unable to identify you. You will not profit from any future study or collaboration that uses your sample. We will only pass on samples which are identified by a code number and we will not pass on information that allows external collaborators to identify you.

Q. Will I be able to request that my samples are destroyed?

A. Yes. If you decide that you no longer wish to take part in the study, we will ask you whether you want us to destroy all the samples we have collected. If you opt to have your samples destroyed we will do this. If you do not request us to destroy the samples we may still use them as described in this leaflet. In the extremely unlikely event that you lose the capacity to consent for the study (e.g. a serious illness), we will continue to use the samples collected prior to that point.

Q. Will any genetic tests be performed?

A. Yes. We plan to address a number of questions regarding genetic associations of pregnancy complications. As with the other blood tests, it is impossible for us to list every possible genetic test. Again, therefore, you would be allowing us to use these samples as a gift, i.e. that you would be giving us permission to do whatever genetic analyses we would see as helpful, for example, in identifying new tests for complicated pregnancy. We will not inform you of the results of any genetic analyses. We will not reveal these results to any third party outside the sphere of research, such as an insurance company. Moreover, the Association of British Insurers will not ask for nor take into account the result of any genetic test done for the purposes of research. Hence, the genetic testing we perform will have no impact on you, positive or negative.

Q. Will you report any result that allows identification of your baby's paternity?

A. No.

Q. Will I be told the results of any of the ultrasound scans?

A. You will be told all the information which is normally given to women at the time of their routine scans at 12 and 20 weeks gestation. However, we will obtain additional measurements at the time of the 20 week scan and at the time of the research scans at 28 and 36 weeks of gestation. You will not be told the results of the additional information obtained for the purposes of the research study. This is because there is no evidence at the moment that making this information available improves the outcome of the pregnancy. The NHS mandates that women should not routinely be scanned in later pregnancy as it does not improve outcome. One of the aims of this research is to see whether additional routine scanning may have a role that previous

studies have missed and, in order to achieve this goal, we need to scan women in this study without acting on some of the specific elements of the scan result.

However, there are five things we will tell you.

1. We will let you know if the placenta is low at the time of the research scans at 28 and 36 weeks of gestation.
 2. We would inform you if we found that your baby had an abnormality at the time of the research scans at 28 and 36 weeks of gestation. However, both of these can usually be seen at the 20 week scan and it is uncommon to see abnormalities for the first time in later pregnancy.
 3. We will let you know whether your baby is presenting head first or bottom first. At 28 weeks, this is for interest only. But this is useful to know at 36 weeks.
 4. We will tell you if the fluid around the baby is severely reduced at the time of the research scans at 28 and 36 weeks of gestation.
 5. We will tell you if the blood flow to the placenta is critically abnormal at the time of the 28 or 36 week scan.
- In the event of any of the above, we will refer you to a midwife, obstetrician or specialist in Maternal-Fetal Medicine, as appropriate.

The elements of the scan that we will not reveal are the measurements of the size of the baby, the measurement of the fluid around the baby and the measurements related to the blood flow to the placenta. However, as described above, we will reveal critically abnormal levels of fluid and blood flow.

Q. Why will you not inform me if my baby appears to be small or large?

A. Estimating the size of the baby is associated with errors. In many cases, the scan gets the size of the baby badly wrong and this can lead to unnecessary intervention. Current clinical guidelines recommend against using ultrasound routinely in this way as it may cause more harm than good. One of the aims of the study is to determine if there is anything we can add to scan results – such as the results of blood tests – which could improve their ability to predict outcome. However, if your midwife or doctor thinks that your baby's size should be assessed for some other reason, they will book a scan in the Rosie Hospital's main ultrasound department as they would for any other patient.

Q. What will happen to the results of the research study?

A. We will publish the results of this research in scientific journals. We will place details of our findings on the Department of Obstetrics & Gynaecology web site (see below). However, no-one will be able to identify you as one of the participants in the study.

Q. Who is organising and funding the research?

A. The study is funded by the Wellcome Trust and research in the department is also supported by the National Institutes of Health Research, the R&D arm of the NHS.

Q. Who has reviewed the study?

A. The scientific case for performing the study was assessed by the Wellcome Trust who sent the study description to six external peer reviewers. The ethics of the study was assessed by an independent group of people, the Essex Research Ethics Committee. Their role is to protect your safety, rights, wellbeing and dignity. Both the scientific case and ethics of the study have been reviewed and given favourable opinion.

Q. Contact for Further Information

A. Prof GCS Smith. The research going on in the Department of Obstetrics & Gynaecology is described on the web site (<http://www.obgyn.cam.ac.uk/>) and, ultimately, the results of this study will be posted there as well. If you have any specific queries, you can also write to the department at Box 223, The Rosie Hospital, Robinson Way, Cambridge, CB2 2SW or telephone 01223 769262.

Q. Who insures the study?

Cambridge University Hospitals NHS Foundation Trust, as a member of the NHS Clinical Negligence Scheme for Trusts, will accept full financial liability for harm caused to participants in the study caused through the negligence of its employees and honorary contract holders. There are no specific arrangements for compensation should a participant be harmed through participation in the study, but no-one has acted negligently.

The University of Cambridge will arrange insurance for negligent harm caused as a result of protocol design and for non-negligent harm arising through participation in the study.