The International Fetal and Newborn Growth Standards for the 21st Century

INTERBIO-21st FETAL & INFANT GROWTH STUDY

PATIENT INFORMATION SHEET

We would like to invite you to take part in the INTERBIO-21st Fetal & Infant Growth Study, which aims to investigate the effects of nutrition on fetal growth and development.

Before you decide, we would like you to understand why the research is being done and what it would involve for you and your baby.

Please read this information sheet carefully.
One of our team will go through it with you and answer any questions you have. We suggest this should take about 15 minutes.

Talk to others about the study if you wish.

Part 1 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 not clear.

Oxford Maternal & Perinatal Health Institute
Green Templeton College
Woodstock Road
Oxford OX2 6HG

Nuffield Department of Obstetrics & Gynaecology
University of Oxford
Women’s Centre, John Radcliffe Hospital
Oxford OX3 9DU
PART 1: The purpose of the study and what will happen to you if you take part

What is the purpose of the study?

We plan to investigate the effects of nutrition on fetal growth and development until infants have reached the age of 2. To do so, we would like to collect from mothers and babies:

- information about newborn and pregnancy outcomes, and infant measurements at 1 and 2 years of age.
- biological samples to study how maternal nutrition and the control of genes (epigenetics) influence the growth of the fetus

We would also like to donate some of the samples to the Oxford Pregnancy Biobank\(^1\) for future studies into the causes of problems in pregnancy. For more information on the Biobank, please go to: http://www.oxfordbrc.org/research/women-and-paediatrics/338/.

The overall aim is to use the information and samples we collect to make pregnancy even safer and develop effective treatments for problems in pregnancy.

This study will take place in seven countries and we hope to recruit around 4000 volunteers, 700 of whom will come from Oxford. This study is unique in its size and in assessing mothers and babies from all over the world.

Why have I been invited?

We are inviting all women planning to deliver at the John Radcliffe Hospital who are over 18 years old and less than 14 weeks’ pregnant. The pregnancy must have been conceived naturally; we are not recruiting women with twins or triplets.

Do I have to take part?

It is up to you to decide whether or not you wish to take part. Your decision will not affect the care you receive in any way. We will describe the study and go through this information sheet with you. If you agree to take part, we will then ask you to sign a consent form. If you have any questions or concerns after reading this leaflet, our research midwife will be happy to answer them. You can also call her on the number on the back of this information leaflet.

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

You are free to withdraw from the study at any time, without giving a reason. This would not affect the care you receive in any way. Any stored data that identifies you, and any samples that you have donated would be destroyed.

\(^1\) REC reference: 09/H0606/10
What will happen to me if I take part?

If you agree to take part in the study, you would be offered 6 ultrasound scans at 4-6 weekly intervals. At each scan, we would measure your baby, and the blood flow to the placenta and the baby. At each scan visit, we would also measure your blood pressure, heart rate, temperature, breathing rate and oxygen saturation (using a small device attached to a finger for a few seconds). Each session takes approximately 45 minutes in total.

In addition, we would ask you to donate biological samples for our studies and the Oxford Pregnancy Biobank (in other words for future approved studies):

- At the first visit to the antenatal clinic, we would ask you to donate a small blood sample of 12ml (3 teaspoons) in addition to the blood sample taken as part of your routine care.
- At each scan visit we would ask you to donate a 5ml urine sample (1 teaspoon).
- At delivery, we would ask to take a 12ml (3 teaspoons) blood sample from the umbilical cord, and 9 small pieces (the size of a 5 pence coin) of your placenta after your baby has been delivered.
- Lastly, we would also like to collect a very small sample (the size of a 2 pence coin) of faeces, only if you have opened your bowels during the delivery.

We would like to weigh your baby when he/she is born and measure your baby’s length and head circumference, as well as take measurements around your baby’s mid-arm, leg and tummy if possible, to help us understand how babies grow.

We would also like to find out the relative amount of fat and other tissues (body composition) in your baby’s body after birth. This is done using a ‘PEA POD’, which is a computerised weighing scale and measuring machine. Your baby would be undressed, weighed and then placed in a cot for 2-3 minutes. The cot has a window (see picture) so that you can see your baby and he/she can see you.

These techniques have been used thousands of times and babies are usually calm when being measured. In the unlikely event that your baby became distressed for any reason then we would stop straight away and would only continue if you were happy. The whole procedure should take no longer than 30 minutes. This includes time to undress and re-dress your baby, prepare the PEA POD, and perform repeated measurements to ensure they are as accurate as possible.
When you return home after leaving hospital, we would like to measure your blood pressure, heart rate, temperature, breathing rate and oxygen saturation, once a day for two weeks, with simple equipment that we will supply. A midwife will visit you at home to help you with this. These measurements should take no longer than 10 minutes each day.

We would then like to follow-up all children at the time of their 1\textsuperscript{st} and 2\textsuperscript{nd} birthdays (although we can see them up to 2 weeks either side of these dates) to record some of your baby’s milestones (as listed in the “Red Book”). We would contact you, and your GP, by letter about these appointments nearer the time, to invite you to attend. The two follow-up appointments would be with our follow-up Measurement Team at the Women’s Centre, John Radcliffe Hospital, and should last no longer than 30 minutes. At these appointments, we would repeat the measurements described above, except for the PEA POD measurements that are only carried out in younger babies.

If your baby is born prematurely we would like to take extra measurements of his/her weight, length and head circumference every 2 weeks for the first 8 weeks after your baby is born; thereafter, every month until your baby is 8 months old, and then at 15, 18 and 21 months. We would also like to measure body composition with the PEA POD machine at each visit until your baby weighs more than 9 kg (the limit of the machine). These appointments will be with the team at the hospital as described above. We will then invite you to attend the 1 and 2-year appointments as described above.

**Expenses and payments**

You may claim back travel expenses for the additional ultrasound and follow-up appointments. There is no payment for donating samples to our study or to the Oxford Pregnancy Biobank.

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

To minimise inconvenience and unnecessary discomfort, the blood sample for research purposes would be taken at the same time as blood is taken as part of your routine care.

The ultrasound measurements themselves are safe and carry no risk to your baby. If our measurements showed any problems with your baby’s growth then we would report these to your doctors who would arrange appropriate monitoring of your baby.

The baby measurements themselves are safe and carry no risk. Babies do occasionally become upset during measurements, as explained above. In the unlikely event that your baby became distressed for any reason then we would stop straight away.

We expect most of the babies we follow up to be entirely healthy and to have normal growth. If, however, our measurements showed any problems with your baby’s growth then we would report these to your GP who would arrange appropriate monitoring of your baby.
What are the possible benefits of taking part?

Taking part in this study would not usually benefit you or your baby directly. The only situation where there might be direct benefit would be if we detected growth problems, which might allow earlier monitoring and/or investigations by your doctors. Taking the blood pressure, heart rate, temperature, breathing rate and oxygen saturation measurements would allow us to develop new charts for use in the NHS to help save mothers’ lives. Donating samples for research is not important for your care, so that if you prefer not to donate you should feel free to say so. The rest of your care would be entirely unaffected. However, if you do take part you will be helping us to learn more about pregnancy and newborn outcomes, which will benefit others in the future.

What if there is a problem?

Any complaint about your involvement in the study or any possible harm you might suffer will be addressed. The detailed information on this is given in Part 2.

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. The details are included in Part 2.

This completes Part 1.

If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 (next pages) 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. It would not affect the care you receive in any way. If you withdraw from the study, any stored data that identifies you would be destroyed. If you withdraw after you have donated biological samples, you will be asked if you are happy for the samples to be used and, if not, they will be destroyed.

What if there is a problem?

If you have concerns about the way you have been approached or treated during the course of the study, you can contact Professor Stephen Kennedy, Clinical Director, Women’s Services, Oxford University Hospitals NHS Trust and Head of the University Department of Obstetrics & Gynaecology, on 01865 221003. If you wish to complain about any aspect of the way in which you have been approached or treated, you should contact the University of Oxford Clinical
Trials and Research Governance office on 01865 743005. If you remain unhappy and wish to complain formally, you may also follow the normal NHS complaints procedure. Please see: www.nhsdirect.nhs.uk/articles/article.aspx?articleId=569 for more information.

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 University of Oxford but you may have to pay your legal costs. Compensation for harm arising from an accidental injury and occurring as a consequence of your participation in the study will be covered by the Oxford University Hospitals NHS Trust.

**Will my taking part in this study be kept confidential?**

Any information that is collected about you during the course of the research will be kept strictly confidential. Our data manager, who has a duty of confidentiality to you and your baby as research participants, is the only person able to identify you and your baby. If you choose to continue with the study, your and your baby's results and pictures will be held anonymously in a secure database to which only the research team will have access.

Authorised representatives of the University of Oxford may look at the anonymised results to check that the study is being performed correctly. No individual participants will be identified when the results of the study are published. Any information that leaves the hospital will have your name removed so that you cannot be identified.

The data will be retained for 20 years after the end of the study in the event that future discussions about pregnancy and newborn outcomes require the data to be reanalysed. After 20 years, the data will be disposed of securely. You have the right to check the accuracy of data held about you and your baby, and to correct any errors.

**What will happen to any samples I give?**

For confidentiality reasons, your name will be removed by the Research Midwife from all biological samples and replaced by a number. The samples will either be used as soon as possible to study how nutrition and genes influence the growth of the fetus or stored in the Oxford Pregnancy Biobank for future, approved research. The results from any tests carried out on these samples will have no bearing on your current or future clinical care.

**Involvement of hospital doctors and General Practitioner (GP)**

In clinical research such as this, it is our responsibility to inform your hospital doctors and GP that you have agreed to take part in this study. This is to ensure that your baby is healthy at the time of participation and remains well during the course of the study. If the study did show any problems with your baby's growth we would also inform your hospital doctors and GP of this so that they could monitor and/or investigate this as appropriate.
What will happen to the results of the research study?

The results will be prepared for publication in scientific journals and presentation at international meetings. We can provide you with a copy of the papers after publication if you wish. Your name will not appear in any report or publication. Some of the data from the study may be included in the PhD thesis of one or more of the researchers. Your identity will be protected at all times.

Who is organising and funding the research?

The research is being carried out by the Nuffield Department of Obstetrics & Gynaecology at the University of Oxford, and is being funded by the Bill and Melinda Gates Foundation. The doctors involved in the research are not being paid to include you in the study and have no conflicts of interest with regards to the study. The Oxford Pregnancy Biobank is supported by the Oxford Partnership Comprehensive Biomedical Research Centre with funding from the Department of Health’s National Institute for Health Research.

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, well-being and dignity. This study has been reviewed and given favourable opinion by the South Central – Oxford C Research Ethics Committee.

This completes Part 2.

You may keep this information leaflet for your records.

If you have any questions, please contact us as above.

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.
Further information and contact details

If you have any questions, please do not hesitate to contact Fenella Roseman, our Research Midwife by:

    Telephone:  07837846234
    Email:      fenella.roseman@obs-gyn.ox.ac.uk
    Post:       NDOG, University of Oxford, John Radcliffe Hospital, Women's Centre, Level 3, Headington, Oxford OX3 9DU

You can find our website at www.INTERGROWTH21.org.uk