



**Pregnancy Outcome
Prediction Study:**
*Trans-generational and
Adult Review*



**UNIVERSITY OF
CAMBRIDGE**

Some years ago, you were kind enough to participate in the POP study during your pregnancy. We remain very grateful for your contribution. The scans, samples, and information that each POPS mum contributed have given doctors worldwide important insights into how we can improve care of mother and babies during pregnancy.

Some important findings of the POP study include:

- Doing extra scans late in pregnancy can treble our chance of detecting which babies are struggling to grow. These babies are at higher risk of complications, so this information is crucial.
- New insights into gestational diabetes, which are changing the way we test mothers during pregnancy.
- There are particular patterns of growth in the womb that may increase the risk of needing emergency Caesarean sections.

You can read more about what POPS has achieved so far on the study website:

<https://www.obgyn.cam.ac.uk/research/pops-2/>

The original aim of the POP study was to investigate the immediate outcomes of pregnancy, such as poor growth of the baby in the womb. We are now launching a new study to look at how else we can use pregnancy findings to improve health and predict risk of health problems throughout life for mothers and their babies.

The new study is called POPStar (POPS: transgenerational and adults review). We would very much like you to be part of this new study, and have included information about POPStar. If you are happy to go ahead, nothing further is required of you at this time. To undertake the POPStar study we will electronically link the information collected in POPS to your later health records (see text below for details). Of course, there is no obligation whatsoever to take part and information on how to opt out is also included.

With best wishes, and many thanks for your help with our research efforts so far,

The POPStar Team (thepopstarstudy.co.uk)

Email: popstarstudy@medschl.cam.ac.uk

Frequently asked questions for participants

What is the purpose of POPStar?

The POP study, which recruited pregnant women between 2008 – 2012, looked at ways to predict which women will have complicated pregnancies. The information you have helped us collect during your pregnancy, from interviews, blood samples and extra scans, is unique and has been used to draw important conclusions about health of mothers and babies during pregnancy. Now, we want to understand how factors before and during pregnancy (e.g. genes, hormones, baby's growth in the womb) and childbirth affects mothers' long-term health as well as children's health, growth and development. To do so, we would like to find out more about you and your child's health and wellbeing since the POP Study.

Why have myself and my child been selected to be part of this study?

You were part of the POP (Pregnancy Outcome Prediction) Study.

What is required from me and my child for the POPStar study?

For the POPStar study neither you or your child will be required to give up any of your time. We would like to collect some additional information from records that the NHS and other public organisations hold about you and your child.

Unless you tell us not to, we will link the information you have already provided us in the POP Study to information that the NHS and other public organisations hold about you and your child (e.g. GP and education records) now and in the future. This allows us to look back and see if any information can be used as an early warning for any condition you or your child may have or develop in the future. The information we collect will be kept confidential at all times. You are free to opt out or stop this access at any point without giving a reason. We have included more detailed information on record linkage in the section below.

We would be happy to hear from you if you would like more information or have specific questions about the study. You can contact us via:

phone (01223 763405)

email (popstarstudy@medschl.cam.ac.uk)

or our online form (www.thepopstarstudy.co.uk).

Opting out

If you wish to opt out you can do this very simply at any time via our online form (www.thepopstarstudy.co.uk), email (popstarstudy@medschl.cam.ac.uk) or by contacting the study team at:

POPStar Study Team
University Department of Obstetrics and Gynaecology
The Rosie Hospital
Cambridge
CB2 2SW

If you send an opt-out via letter or email, please provide your full name, your child's name and the date that your child in the POP study was born so that we can be sure to remove the correct participant. Please provide a return address so that we can acknowledge receipt.

We may ask you your reasons for opting out to try to improve the study for other participants, but there is no obligation to provide any reasons.

What will happen next?

If we don't hear from you within a month of this letter, we will go ahead with the analysis as planned. However, the opt-out option remains available at all times.

All the information retrieved from your other records, and the results of tests performed on the samples you have donated to the POP Study will be held on a secured anonymous research database. This will be used in medical research to understand the associations between pregnancy and early life factors on maternal health and children's health and development. None of the research team will be able to see which information belongs to which mother and child – all of the analysis will be done on de-identified data.

In the future, other studies may be carried out and we might contact you to invite you and your child to take part. You will be provided with full information about each of these studies and will be free to decide whether or not to participate. If you are interested in hearing more about these studies, then you can record your contact details at www.thepopstarstudy.co.uk

Do I have to take part?

This is entirely up to you; your decision will not affect any care you and your child receives at any time. The opt-out option is available at www.thepopstarstudy.co.uk

Are there any risks of taking part?

There is no risk to you or your child.

What are the possible benefits of taking part?

There will be no direct benefit to you and your child from taking part. The information we will gain from the study will help lead to a better understanding of the links between genes, pregnancy, environmental factors and disease. Your participation will contribute to improving healthcare provision and long-term prevention and treatment of a number of different diseases.

What will happen if I change my mind?

If you wish to withdraw from the study, you can do so at any time, without having to give a reason. This will not affect any care you or your child receives. Withdrawal from the study will mean that all the information obtained from you and your child for the POPStar study will be destroyed using the standard procedures employed by the University of Cambridge for confidential information.

Will my information be kept confidential?

Yes. Best ethical and legal practice will be followed to ensure that all information collected about you and your child will be handled in confidence. Information will be stored anonymously, using a study ID number. Codes connecting your individual identity and stored data records will be kept separately. The research database will be stored on a secured drive, password and firewall protected, on University of Cambridge computers, and only accessible by members of the POPStar research team. All of our protocols for data-handling have been scrutinised and approved by an independent review panel.

What will happen to the results of the study?

The results will be summarised on the website at least yearly, and more often when significant findings are made. The results will also be presented at medical conferences and published in scientific journals in an anonymised way. It will not be possible to identify individual participants in any presentations or publications. If you would like to receive study updates directly, then please leave your email or postal address at www.thepopstarstudy.co.uk

Who is funding and sponsoring the study?

POPStar is currently funded by the National Institute for Health Research (NIHR) Cambridge Biomedical Research Centre and sponsored by University of Cambridge.

Who has provided ethics review of the study?

All proposed research studies are examined by an independent group of people, called a Research Ethics Committee. This study has been reviewed and approved by Cambridge Central Research Ethics Committee, Ref: 18/EE/0036.

Who should I contact for further information?

If you want more information before deciding, or have any queries about anything concerning the study, please feel free to contact the recruitment team on 01223 763405 or e-mail us popstarstudy@medschl.cam.ac.uk.

This section provides more information about record linkage and data security.

Thank you for considering participating in POPStar.

Linkage to existing routine data

What information will be collected? Why do you link data?

The NHS maintains routine medical and other health-related records (via NHS Digital) on all patients so they can provide health services to us when we need them. The information may include, for instance admissions or attendances at hospitals and records of specific conditions.

Government departments collect a range of information about all of us for administrative purposes. This includes education records such as results on national tests and requirement for special educational needs (National Pupil Database).

While we can learn about people's health, experiences and behaviour by asking direct questions, we can often get a more complete assessment of the health of the participants using information from administrative records using a method called data linkage.

How is the data collected and linked?

In order to access the information, we will provide some necessary personal details such as your name, date of birth, and address to the relevant NHS or government departments holding the information (NHS Digital/ National Pupil Database). These personal details will only be used to identify your information. Before any information is sent back to us, your name and other details will be removed. None of the information we had previously collected in the POP Study will be disclosed to other NHS or government departments for any purpose. When we get the data back it will no longer be linked to your personal information – we will only know who is who using a special numeric code.

How long will my consent last?

We would like to continue to follow-up on the health of you and your child until your child reaches the age of 16. With the study updates that we post annually, we will remind you that you are free to

withdraw your consent at any time. After the end of the study, data will be held in anonymised form for up to 20 years.

What about my child's information?

We will like to continue to follow-up on your child's long-term health. We need to seek parental consent to collect information on your child aged under 16. We understand that some children would be able to make this decision on their own behalf. Please discuss this with your child as appropriate and make the decision that represents your child's wishes. You may find it helpful to use the information available for children between 5-8 years old and for children between 8-10 years old on the study website (www.thepopstarstudy.co.uk). You can withdraw your consent at any time.

What about data security?

All information we hold about you and your child will always be strictly confidential. Any information we need to exchange with NHS and government departments will be encrypted and sent via secure transfer systems.