Born in Scotland in the 2020s – Pilot Study

Study Participant Information Sheet

You are invited to take part in a research study. To help you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish. Contact 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.

What is the purpose of the study?

Born in Scotland in the 2020s (BIS) is a **study** that aims to collect information (data) from a group (called a **cohort**) of pregnant mothers and their baby/babies during the pregnancy and at **birth**. This type of study is called a **birth cohort study**.

We know from other birth cohort studies that the health and wellbeing of the mother during pregnancy can affect the health and wellbeing of the baby, both during development in the womb and whilst growing in childhood. In this study, we hope to collect data which will help medical professionals to give better care to pregnant mothers and babies, and make a positive difference to future families.

In this pilot study we want to find out the best way to set up this new birth cohort in Scotland. A pilot study means it is a small-scale study, designed to help us decide how best to set up a larger study. We would like to invite you to take part in this pilot study. We plan to use routinely collected data and biological samples where possible, so that you don't have to do anything extra to take part in the study.

We intend to enrol about 1,000 women into this pilot study and use the findings to plan a much larger study across the whole of Scotland.

We may also ask you if we can collect some additional samples from you and/or your baby at the time of birth (such as a blood sample or placenta), or invite you to take part in other smaller studies but these are optional and you can still be a part of this study without joining additional studies. If you decide you would like to take part in any additional studies, we will provide you with more detailed information at the time, about exactly what is involved and we will be sure to get your informed consent.

Why have I been invited to take part?

You are a pregnant woman aged 16-50 years, living in one of our study areas; Edinburgh & The Lothians, The Borders or Greater Glasgow and Clyde] in Scotland and planning to give birth in Scotland and currently pregnant (at any gestation).

Inclusivity statement

Our team is committed to making research in pregnancy inclusive. We use terms such as 'women', 'maternity', 'breastfeed' and so on, throughout our website, publications and social media accounts, to refer to those who are planning to become pregnant, are pregnant, give birth and/or use their breasts to feed a child. We acknowledge that not all people who are pregnant, give birth, and/or breastfeed a child identify as women. It is important that evidence-based care for maternity, perinatal and postnatal health is inclusive and tailored to an individual's wishes.

Do I have to take part?

No. It is up to you to decide whether or not to take part but before deciding you might want to discuss this with your family or friends. It's a good idea to think about it for at least 24 hours before deciding to take part.

If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time without giving a reason. Deciding to not take part or withdrawing from the study after you have joined will not affect the healthcare that you receive, or your legal rights. If you have any questions about taking part or withdrawing from the study, please email the research team on researchmidwives@nhslothian.scot.nhs.uk or telephone on 0131 242 2480.

If you do not have access to an electronic device, we can post a paper copy to you on request. Please contact the study team to discuss other formats, such as different languages: either email researchmidwives@nhslothian.scot.nhs.uk or telephone on 0131 242 2480.

What will happen if I take part?

If you would like to consent to participate in the pilot study, once you have read this leaflet you can access the study website by scanning the QR code below or visit the study website www.edin.ac/borninscotland-join and the following process will happen:

SCAN ME

i) You can click to take part, and access the consent form. You will need to read the consent form carefully and give informed consent to become a study participant. You can choose to opt-in to the collection of **all** of the samples/data or only **some** of the samples/data. We would prefer if you opt-in as early as you can in your pregnancy so that we can collect as much information on your pregnancy as possible. However, we understand that you may prefer to join this study later on in your pregnancy and that is fine too.

You can also choose to opt-in at any point during your pregnancy, by visiting the website, contacting the study team at researchmidwives@nhslothian.scot.nhs.uk or telephone on 0131 242 2480.

ii) When completing the consent form on the website, you will need to provide us with some basic personal and demographic information, like: your name, date of birth, address, phone number, email address, GP practice details, GP name, weight, height. Other information may be requested.

iii) We will gather routinely collected data from the TrakCare system or the BadgerNet Maternity Care system; this could include details of your pregnancy such as any complications and your previous pregnancy history. We will retrieve your blood samples from the hospital labs that would otherwise be discarded after they have been used for routine clinical tests. All the information that we collect will be anonymised so that none of your data or biological samples can be traced back to you.

iv) Blood samples will be processed and kept in the Edinburgh Reproductive Tissue Bio Bank (ERTBB). All the information that we collect will be anonymised so that none of your data or biological samples can be tracked back to you.

v) NHS Lothian are not responsible for the security of the device you use to upload your information however, all of the information you provide will be via a secure link and the information you provide will be stored securely on the REDCap database at the Edinburgh Clinical Trials Unit/University of Edinburgh. REDCap is a secure web application used for online surveys and databases (www.project-reccap.org).

vi) We plan to use these leftover blood samples to study how your health relates to the health of your baby. An example of this would be to investigate levels of cotinine - a product found in the blood that can tell us whether someone has been exposed to smoke. We will measure this in all women to look at the links between smoke exposure and baby birth weight.

vii) We will ask for your consent to use some of your leftover blood to take a **DNA sample**, to study the health of you and your baby. DNA (deoxyribonucleic acid) are molecules in your body that contain all your genetic information, it's like your instruction manual for life. We will analyse the DNA sample to investigate genes that may be linked to and influence the birthweight of your baby. If you do not want us to take a DNA sample you can still be part of this study. We understand that you may have concerns about what DNA analyses will be carried out on these samples and what happens to the results. We will happy to provide additional information to; you can contact us via the study website or by phone or email.

viii) We may contact you during your pregnancy to ask for extra consent through the Edinburgh Reproductive Bio Bank to collect **additional samples** from you at the **time of birth**, for example we may ask to keep the placenta after it has been delivered, or to take a small hair clipping from your baby. The collection of these additional samples is optional and will not affect your inclusion in this study.

What are the possible benefits of taking part?

There are no immediate benefits for you in taking part in this study, though the findings will be important for us in designing the larger study. We hope that the larger Born in Scotland study will improve what we know about health and wellbeing in pregnancy and the health, wellbeing and development of babies. This may help medical professionals to provide better treatment to women during pregnancy and predict the long-term health of the child.

What are the possible disadvantages of taking part?

It is not thought that there are any disadvantages of taking part in this study. If you find that you are not enjoying or benefiting from participating in the study, you can withdraw at any time. You can also ask that any information you have already provided be removed from the study.

What if there are any problems?

It is vital that if you feel that you need more information or if you have a concern about any aspect of this study, please contact your community midwife, GP, local hospital, or a member of the Born in Scotland research team at researchmidwives@nhslothian.scot.nhs.uk or telephone on 0131 242 2480, who will do their best to answer your questions. The research team will check this email inbox routinely and will answer within 5 working days. If you wish to make a complaint about the study, please contact NHS Lothian using the contact details at the end of this information sheet. In the unlikely event that you feel you have been harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against NHS Lothian but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

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

You are free to withdraw from this study at any point without giving a reason. Withdrawing will not affect the healthcare that you receive, or your legal rights. To withdraw from the study, you can visit the study website to complete a withdrawal form on www.edin.ac/borninscotland or contact the study team via researchmidwives@nhslothian.scot.nhs.uk or via telephone 0131 242 2480 and they will withdraw you from the study. You won't need to take any further action. You will have the option of:

(i) Withdrawal from the Born in Scotland study but allow us to retain the data/samples collected from you up to that point.

OR

(ii) Withdrawal from the Born in Scotland study but allow us to retain the data/samples collected from you up to that point, and also collect the routine NHS data at 6-12 weeks at the postnatal check by your health care professional.

OR

iii) Withdrawal from the Born in Scotland study and we will remove all the data/samples collected from you up to that point and will not collect any further data.

What happens when the study is finished?

At the end of the research we will analyse the data and publish the results. We will also publish a summary of the results online on the Born in Scotland website www.ed.ac.uk/born-in-scotland. This will give you information about what we have found through this study. The data from the study will be stored on a secure server for at least 3 years. Biological samples will be stored for 25 years in University of Edinburgh freezers. All data and samples will be stored anonymously. Anonymised data and tissue samples will be made available to accredited researchers for additional analyses.

Will my taking part be kept confidential?

All the information we collect during the course of the research will be kept confidential and there are strict UK laws which safeguard your privacy at every stage.

How will we use information about you?

We will need to use information from you and from your medical records (TrakCare or BadgertNet system) for this research project. This information will include your NHS CHI number, name, date of birth, contact details and will be stored securely on the REDCap database

Research staff will use this information to do the research or to check your records to make sure that the research is being done properly.

Research staff who do not need to know who you are will not be able to see your name or contact details. Your personal details will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are the choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason. We will ask if we can keep the data/samples we have collected up to this point.
- If you choose to stop taking part in the study, we would like to continue collecting information about your health from your TRAKCare/BadgerNet system records. If you do not want this to happen, tell us and we will stop.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information:

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from www.hra.nhs.uk/patientdataandresearch

- by asking one of the research team on 0131 242 2480
- by sending an email to: borninscotland@ed.ac.uk or
- by contacting a Data Protection Officer:

University of Edinburgh
Data Protection Officer
Governance and Strategic Planning
University of Edinburgh
Old College
Edinburgh
EH8 9YL
Tel: 0131 651 4114
dpo@ed.ac.uk

NHS Lothian
Data Protection Officer
NHS Lothian
Waverley Gate
2-4 Waterloo Place
Edinburgh
EH1 3EG
Tel: 0131 465 5444
Lothian.DPO@nhs.net

What will happen to the results of the study?

The study will be written up as a paper and/or presented at a conference. You will not be identifiable in any published results. A general summary of the study's findings will be available on the Born in Scotland website. If you would like to receive anonymised results at the end of the study, please contact us at researchmidwives@nhslothian.scot.nhs.uk.

Who is organising and funding the research?

This study has been organised/sponsored by the University of Edinburgh and NHS Lothian and funded by the Medical Research Council. Edinburgh Clinical Trials Unit, which is part of the University of Edinburgh, provides database support for the study. The Edinburgh Reproductive Tissue Bio Bank (ERTBB) will store tissue and blood samples.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee. A favourable ethical opinion has been obtained from South East Scotland REC 02Ethics Committee. NHS management approval has also been obtained.

Researcher Contact Details

If you have any further questions about the study, please contact the research team at researchmidwives@nhslothian.scot.nhs.uk or telephone 0131 242 2480.

Independent Contact Details

If you would like to discuss this study with someone independent of the study, please contact Dr Sarah Murray (Clinical Lecturer in Obstetrics) at Sarah.Murray@ed.ac.uk.

Complaints

If you wish to make a complaint about the study, please contact NHS Lothian:

Patient Experience Team
2 – 4 Waterloo Place, Edinburgh, EH1 3EG
Tel: 0131 536 3370 Email: feedback@nhslothian.scot.nhs.uk