Participant Information Sheet

Exploring the views and preferences around data governance of participants in the Born in Scotland in the 2020s project.

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?

This research project is exploring a new way to manage data in health research, called a "Data Trust." This project is part of the *Born in Scotland in the 2020s* (BiS) study, which collects information from pregnant mothers and their babies to improve healthcare for future families.

A "Data Trust" is a new idea that would allow people to put their data and data rights into an independent organisation, managed by “trustees” who make decisions on their behalf. This approach would give individuals more control over how their data is used, allowing them to input into decisions about how it is used and to choose trustworthy people to manage it.

The idea of a trust can be difficult to understand, but it is similar to how someone might manage land on behalf of others, ensuring it is used according to the owner’s wishes. In this case, the "land" is data and the trustees are responsible for using that data in line with the wishes of the individuals that provide it.

In this project, we are working with researchers at the University of Warwickto find out what existing participants in the BiS study think about the Data Trust idea. To do this, we will run a focus group with up to 15 participants to ask questions about your views and preferences.

We will also ask you to watch a short video explaining the Data Trust idea and ask you to share your opinions on:

- The Data Trust idea
- What would you like a Data Trust to achieve?
- Whether you would trust a Data Trust to manage your health data?

Why have I been invited to take part?

You have been asked to take part as you are an existing eligible BiS participant and you previously consented to being contacted about future related research projects. You have the English language skills required to watch a video and participate in discussion.

Do I have to take part?

No, it is up to you to decide whether or not to take part.

If you do decide to take part you will be given this information sheet to keep and be asked to sign an additional consent form for this related study. If you decide to take part you are still free to withdraw at any time and without giving a reason. You can find our more including to take part by visiting the QR code below, our website Born In Scotland Data Trust | Edinburgh Pregnancy Research Centre (https://edinburgh-pregnancy-research.ed.ac.uk/current-studies/born-in-scotland-data-trust) or by registering your interest at: borninscotland@ed.ac.uk

Deciding not to take part or withdrawing from the study 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 borninscotland@ed.ac.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 borninscotland@ed.ac.uk or telephone on 0131 242 2480.

What will happen if I take part?

You are invited to join an in-person focus group at [location] hosted by researchers from the University of Edinburgh. The focus group will explore your thoughts on a new model for managing data for health research, called a "Data Trust." You will be asked to watch a short video (approx. 3 minutes) and to participate in a discussion. The video can be viewed here at our website: Born In Scotland Data Trust | Edinburgh Pregnancy Research Centre

The discussion will be audio recorded. Researchers will also take notes during the session. These recordings/notes will be securely sent to an external transcription company to be typed up (transcribed) for research purposes by 1st Class Secretarial Services.The anonymised transcription will be shared with our colleagues at the University of Warwick who work with us on the Data Trust Project (You can find out more about this collaboration at our website: Born In Scotland Data Trust | Edinburgh Pregnancy Research Centre). An anonoymised transcript is one where your name and any identifying information you provided has been removed.

You have the right not to answer any questions that you do not want to answer, and you are free to leave the focus group at any time without giving any reason.

The focus group will last for a minimum of 1 hour and a maximum of 2 hours with breaks available as needed. You can be reimbursed for reasonable travel expenses.

Attendees are welcome to bring children in their care to the event. Childcare will be available within the room.. While some toys and baby changing facilities will be available, you are responsibility for the safety and wellbeing of any children that attend this event with you.

Is there anything I need to do or avoid?

Please ensure you are familiar with the location of the focus group prior to arrival. Before the day, tell the researchers about any dietary, health and access requirements for you and anyone you are bringing with you.

What are the possible benefits of taking part?

There are no direct benefits to you taking part in this study, but the results from this study may help to improve our understanding of your views on Data Trusts and may help to develop a Data Trust model for future real world health research projects.

What are the possible disadvantages of taking part?

The main disadvantage is the time required for the focus group itself. Every effort will be made to keep related correspondence to a minimum. It is not thought that there are any other disadvantages of taking part in this study. If you are not enjoying participating in the study, you can leave (withdraw) at any time without giving a reason.

You will be invited to share your name and views during the focus group, but you will not be identified by name in any of the research outputs like publications in academic journals. With your consent, we will record the focus group for the purpose of transcription, which will be anonymised and analysed for research purposes. As such there are limited possible risks associated with taking part.

What if there are any problems?

If you have a concern about any aspect of this study please contact a member of the Born in Scotland research team at borninscotland@ed.ac.uk or telephone on 0131 242 2480, who will do their best to answer your questions.

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

You can stop being part of the study at any time, without giving a reason. However, if you choose to withdraw after the focus group has taken place, we will not be able to withdraw your contributions to the recorded discussion, but these will be kept in an anonymised format and used for research purposes only.

What happens when the study is finished?

The data you provide will be kept securely as electronic data in a password-protected folder of a secure server, or as paper in a secure location of the University of Edinburgh. Recordings will be kept in a password-protected folder/files and deleted as soon as possible after transcription. After transcription, the recordings/notes will be anonymised (you will not be able to be identified from it). Anonymous data only will be stored securely on the University of Edinburgh server and the server of our project collaborator the University of Warwick. The information you provide will be anonymised and will inform the project outputs for example a publication in an academic journal. Data and materials collected in this research project may be used in closely related future projects, or projects in the general area of health data governance.

The identifiable data collected by this project will be deleted as soon as possible. It will not be disclosed to any other person or organisation outside the project collaborators. Anonymous research data will be retained for use in future related research projects for up to 10 years, as per the University of Warwick data retention policy and up to 10 years as per University of Edinburgh data retention policy.

Further information about the University of Edinburgh Research Privacy Notice is available at: https://data-protection.ed.ac.uk/privacy-notice-research

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 laws which safeguard your privacy at every stage.

How will we use information about you?

Personal identifiable information used will include your: name, e-mail address, telephone number to contact you about this study. Researchers will use this information to contact you about the research and to conduct the focus group. We will ask for permission to access some of Born in Scotland data including your age, ethnicity, postcode and occupation for research purposes. No personal identifiable information will be published.

People who do not need to know who you are, will not be able to see your name or contact details or other details.

We will keep all information about you safe and secure in the password-protected University of Edinburgh.

When the focus group is complete, we will remove personal identifiable information and send the recording to be transcribed to a University-approved transcription service. The transcription will be anonymised and will only be shared with members of the research project team.

Once we have finished the study, we will keep some of the data so we can check the results. We will write up our work in a way that no-one can work out that you took part in the study. Identifiable data will be deleted after the project is finished.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

You can find out more about how we use your information

- Policy and handbook | Data Protection by asking one of the Born in Scotland Research

Team by sending an email to borninscotland@ed.ac.uk

- by telephoning us on 0131 242 2480

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

What will happen to the results of this study?

At the end of the research, we will analyse the data and publish the results and e.g. in an academic journal and/or on the project website and project newsletters. You will not be identifiable from any published results.

Who is organising and funding the research?

This study has been organised by researchers at the University of Edinburgh and sponsored by the University of Edinburgh

The study is being funded by **the Open Collective Foundation.**

Who has reviewed the study?

The study proposal has been reviewed by the Warwick Research Office.
A favourable ethical opinion has been obtained from Edinburgh Medical School Research Ethics Committee (EMREC).

Researcher Contact Details

If you have any further questions about the study please contact the research team at borninscotland@ed.ac.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:

The University of Edinburgh Research Governance Team at resgov@accord.scot