



## **The Baby Hearts Study**

**The Northern Ireland Baby Hearts Study: a study of risk and protective factors for congenital heart disease**

# **Participant Information Sheet**

31/03/14



This study has been funded by Northern Ireland Chest Heart and Stroke.



Additional support has been provided by Children's Heartbeat Trust

We are a research team based at the University of Ulster and the Paediatric Cardiology Department of the Royal Belfast Hospital for Sick Children. We would like to invite you to take part in the Baby Hearts Study which we are conducting throughout Northern Ireland. Please take time to read the following information, which will help you decide whether or not you wish to take part.

### **What is the purpose of the study?**

Every year in Northern Ireland over 200 babies are born with congenital heart disease. In most cases the cause of the problem is not known. The purpose of the Baby Hearts Study is to try and help understand whether environmental factors in early pregnancy increase the risk for babies to be born with heart defects. From the findings we will make recommendations which we hope will help to prevent heart defects in the future.

### **Why have I been chosen?**

We are inviting pregnant women from all areas of Northern Ireland to take part in our study. We are going to be in each maternity outpatient department for one month only – the month for your maternity unit is \_\_\_\_\_. All women who are attending your maternity unit for their 20-week scan appointment during that month are being invited to take part. We hope as many women as possible during this month will take part – all women are of interest to the study and there is no limit to numbers.

### **What will happen to me if I take part?**

If you agree to take part you will be asked to complete a short questionnaire using our iPad, or if you prefer you can complete a paper version. The questionnaire will ask you about your lifestyle, health and wellbeing, and your home and work environment in the three months before you became pregnant and during the first three months of pregnancy.

It is important that you understand that the fact that you will be asked questions about different aspects of your life and lifestyle does NOT mean that they cause congenital heart disease. We do not yet know which factors cause congenital heart disease. Many factors could be involved in causing the heart not to develop properly for any one individual baby. Also, not all babies in early pregnancy are affected by the same things.

In addition to completing the questionnaire we would also like to ask for your consent to collect some information about you and your baby from other sources. The information we would like to collect will include:

- Information collected at your antenatal booking visit which was recorded on the Northern Ireland Maternity System and in the green Maternity Hand Held Record you carried during your pregnancy.

- Information about prescriptions that were issued to you and collected at pharmacies, which you may have taken during the three months before you became pregnant and the first three months you were pregnant. This will be collected from the electronic prescription records held for all of Northern Ireland at the Business Services Organisation of the Health and Social Care Board, and certain medications will be followed up with your GP by a clinical research nurse from the NI Primary Care Clinical Research Network to record information about dosages and the reason for the prescription.

You can decide to give consent to some or all of these. All the data guardians (those legally responsible for the data) will be assured that consent has been given before your information will be shared.

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

All personal information collected about you will be kept strictly confidential. The answers you give in the questionnaire and the information obtained from your health records will be stored electronically, in password protected format, with only your study ID number attached. Your personal details form and consent form (which the researcher will show you) will be kept separately and securely as paper records only, until the end of the study. Only the authorised researcher team will have access to your data. All data storage and processing will be in accordance with the Data Protection Act (1998).

We will not disclose any information that you have shared with us to your GP or maternity team. We are required by law to report anything you disclose that is illegal or an imminent threat to life, however our questions do not cover such matters.

In accordance with current University of Ulster regulations all anonymised data will be stored securely for ten years before being destroyed using secure methods.

### **Do I have to take part?**

Participating in this study is completely voluntary. If you agree to participate in this study, you will be asked to sign a consent form indicating your willingness to participate in this research. If after deciding to take part, you wish to withdraw you may do so at any time without giving a reason. Your decision will not affect the care of you or your baby. If you withdraw from the study, information collected to date will be used unless you specifically ask for it to be deleted, but no further information will be collected.

### **What are the possible benefits of taking part?**

The information you and many other pregnant women give will be compared with the information given by mothers of babies with congenital heart disease. You may feel it a benefit that your participation will contribute to a greater understanding of the causes of babies being born with a heart defect. If you would like to have a copy of the findings once the study is completed please tell Nichola McCullough (see at the end for contact details).

### **What are the possible disadvantages of taking part?**

There are no obvious disadvantages or risks to taking part in the study. It is possible that you may find it uncomfortable to answer some questions. You do not have to answer anything that you feel uncomfortable with. It is also possible that answering some question may reveal an anxiety or worry that you may have about you or your baby. If this happens please let us know and we will arrange for you to speak to a midwife.

### **Token of thanks**

To say thank you for taking part in our study we would like to give you a gift token for £10 that can be used in a number of high street shops.

### **What if there is a problem?**

If you have any concerns about the study please speak to Nichola or any member of the research team (details are provided below) and we will do our best to answer these. If you are still unhappy, the University of Ulster also has procedures in place for reporting, investigating, recording and handling complaints from study volunteers. Further information on the complaints procedure can be found at the University's "Research Ethics and Governance" webpage (<http://research.ulster.ac.uk/rg/0208ResearchVolunteerComplaintsProcedure.pdf>). A formal complaint may also be made through your local Trust. They will have a complaints procedure and you can obtain these details from your hospital.

### **What will happen to the results of the research study?**

This study will take place over three years. When completed, the results will be presented to medical teams and other health professionals with responsibility for care of children with heart conditions and for public health. The results will also be presented at local, national and international conferences and in scientific journal publications. You will not be identified in any report or publication.

### **Who is funding this study?**

The financial support for the study has been granted by Northern Ireland Chest Heart and Stroke, and The Children's Heartbeat Trust.

### **Who has reviewed this study?**

This study has been reviewed and has been given a favourable opinion by the Northern Ireland Research Ethics Committee. An external review process administered by the Northern Ireland Chest Heart and Stroke reviewed the scientific basis of the study before the researchers were awarded funding.

The members of our external advisory committee, who will continue to advise until the end of the study, are:

Ms Zoe Boreland (Midwife)

Ms Katie Boyd (Parent)

Dr Tabib Dabhir (Medical Geneticist)

Ms Heather Reid (Public Health Consultant)

Dr Chris Tennyson (Clinical Psychologist)

### **Members of The Northern Ireland Baby Hearts Study Project Team**

Royal Belfast Hospital for Sick Children:

Dr Frank Casey; Dr Brian Craig, Dr Sinead Callaghan

University of Ulster:

Professor Helen Dolk, Dr Briega M Lagan, Dr Maria Loane, Dr Nichola McCullough, Professor Brendan Bunting, Dr Breidge Boyle, Dr Hafi Saad (PhD student)

### **Further information and contact details**

If you would like to discuss any aspects of the study, or would like to ask any questions or have concerns about the study, please contact either

Project Manager: Dr Nichola McCullough,

Research Fellow, University of Ulster

Tel. 028 903 68053 or Email [n.mccullough@ulster.ac.uk](mailto:n.mccullough@ulster.ac.uk)

Chief Investigator: Professor Helen Dolk,

Professor of Epidemiology and Health Services Research, University of Ulster

Tel. 028 90366639; Email [h.dolk@ulster.ac.uk](mailto:h.dolk@ulster.ac.uk).

**Thank you for taking time to read this information sheet and for considering taking part in our study.**



 **Belfast Health and Social Care Trust**



 **Northern Health and Social Care Trust**



 **South Eastern Health and Social Care Trust**

 **Southern Health and Social Care Trust**  
*Quality Care - for you, with you*

 **Western Health and Social Care Trust**