

If you wish to participate in this study you will be asked to agree to the consent statements below in the presence of a member of the research team.

### CONSENT STATEMENTS

1. I confirm that I have read this leaflet and have had the opportunity to ask questions and have had these answered satisfactorily.
2. I am happy to participate in this project by providing information about my pregnancy and clinical details about the birth of my children
3. I am happy to donate samples, including blood, from myself.
4. I am happy for samples taken during my children's care (e.g. cord blood, heel prick) to be saved for research purposes.
5. I understand that my participation is voluntary and that I may withdraw at any time without my clinical care being affected.
6. I give permission for individuals from regulatory authorities or the NHS Trust to have access to relevant sections of my medical notes and data collected during the study relevant to my taking part in research.

### OPTIONAL CONSENT STATEMENTS

I agree to gift samples and data collected to the PRTB and understand that they may be used in future related ethically approved research. I understand that these studies will be approved by a Steering Committee and my samples will **not** be used for any of the following: sold for profit; used in animal research; used in research into the termination of pregnancy or reproductive cloning; screened for markers predictive of disease (e.g. Huntingdon's). My samples may be provided anonymously to researchers from the UK and abroad including academic organisations and commercial companies.

I agree that information held by the NHS and in my medical records may be used to follow up on my future health status

I am happy for my contact details to be used by the recruiting researchers to inform me about future studies and I give consent for NHS-based staff to access my medical record to check my eligibility for future research.



# The Peninsula Pre/Perinatal Twins Research Bank (PTRB)

## Are you pregnant with Twins?



**We would like to explore how growth in  
the womb can impact on later health.**

## Could you help us?

### **Why are we conducting this research?**

There is increasing evidence that what happens to a baby when growing inside its mother can have a major impact on its future health, but we are not certain why or how this happens. We know that your genes are your body's instruction manual, affecting the way you look, your health, and the way your body works. There is now growing evidence that changes to the chemical switches that control the activity of genes during fetal growth in the uterus can impact on these "instructions" for future health.

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

The PTRB has been set up to help scientists understand how growth in the womb can influence adult health. Twins are ideal for this kind of study as they share the same environment and genetic background, but can develop different health problems in later life. We aim to set up a "bank" of biological samples (e.g. blood, cord blood, placental and a 5 day heel prick sample) which can be taken during routine clinical care and then stored for future study.

### **What does the research involve?**

You will be asked to sign a consent form to say you are happy for samples to be used for research purposes. We will collect a blood sample from you during pregnancy and various biological samples after the babies are born, including cord blood, placental and mouth swabs from the babies. It would also be helpful if we could have the option of a blood sample from the twins biological father. We will ask you permission to access the data collected during routine antenatal care including your height and weight and the babies growth measures

### **What will happen to my samples and data?**

All samples and data will be stored under a unique study ID number under the management of the PTRB. Anonymised data and samples will be provided to researchers upon the approval of the PTRB Steering Committee. This Steering Committee is made up of both lay and scientific members, and will ensure that your samples are only used in well designed studies aimed at improving our understanding of the role of the intrauterine environment (in the womb) on later health.

### **Why have I been invited to participate?**

Your clinician has identified that you are currently pregnant with twins and may be able to help us.

### **Are there any risks or benefits of taking part?**

Donation of blood samples can be uncomfortable but this procedure will be carried out by an experienced midwife/researcher to minimise any discomfort. The project is unlikely to benefit you directly but will help us understand more of what happens in the womb and how this can affect future health.

### **Do I have to take part in this study?**

No, participation is entirely voluntary. It is up to you to decide to join the study. If you agree to take part, we will ask you to sign a consent form like the one overleaf. You are free to withdraw at any point. Participation in the study will not effect your treatment as an NHS patient.

### **Will my participation be kept confidential?**

Yes. We will follow current ethical and legal practice, and all information about you will be handled in confidence. All storage of your data will comply with the Data Protection Act (1989) guidelines.

### **Where can I find out more?**

For independent advice about participation in research you can contact the RD&E Patient Engagement and Experience team on 01392 402093. For further information about the PTRB please contact Bea Knight (Research Midwife) on 01392 408172. If you would like to discuss your donation further with a clinician please contact Mr Myles Taylor (Consultant Obstetrician) on 01392 406587.

### **Who is funding and organising this research?**

The project is managed by the NIHR Exeter Clinical Research Facility It is funded by the National Institute of Health Research which is part of the NHS, and The University of Exeter Medical School

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

This project has been reviewed by the National Research Ethics Service Committee South West - Central Bristol.