

HRB Clinical Research Facility, Galway

Áis Taighde Chliniciúil HRB, Gaillimh

PATIENT INFORMATION SHEET

Study Title: Premature Birth Prediction Study

Principal Investigator: Professor John Morrison

We are inviting you to take part in a research project. Before you agree to take part in the study you must understand why we are doing the study and what will be expected of you if you agree to take part. We are providing you with this information sheet to explain the study to you but if you have any questions about the study after reading this sheet please ask us.

What is the purpose of this study?

Premature birth, also known as preterm birth, is what occurs when a woman delivers a baby before 37 weeks gestation in her pregnancy. It occurs in approximately 6-7% of all pregnancies. It may cause problems when a woman delivers very early i.e. between 24 and 34 weeks of gestation. One of the problems with treating premature labour is that there is no good predictive test to outline women who are more susceptible to it. We are inviting you to participate in a research project which is focused on developing new predictive tests for women who are more prone to delivering early or preterm.

Why have I been chosen?

You have been asked to participate in this study because you have been admitted to hospital with suspected preterm labour.

Do I have to participate?

Participation in this research project is entirely voluntary. You do not have to take part. If you choose not to take part this will not affect the care that you receive from your medical team. If you do agree to take part you will be asked to sign a consent form. However you are free to withdraw from the study at any stage despite signing this form and you are not obliged to give a reason for your withdrawal.

What is required of me if I take part?

On admission to the hospital with preterm labour the criteria of inclusion and exclusion into the study will be evaluated. If you agree to participate in the study you will be asked to sign a consent form. A blood sample will be taken when you have consented to the study and also the following day and a few days later. In addition, if you have delivered within 7 days a blood sample will be taken from the umbilical cord which is attached to the placenta, after the baby is born.

Why do I have to have a blood test?

The blood samples will need to be taken in order to carry out the research. Whenever possible the blood tests will be timed to coincide with when you are having routine blood tests. However, it may happen that some blood tests need to be done solely for the research study.

Are there any risks involved in participating in this study?

No risk is associated to the participation in this study, except the ones associated with the blood test, such as pain or bruise at the site of puncture and a possible, although low, risk of infection.

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What will I do if I have more questions?

If you have questions about any aspect of this study you should contact the Principal Investigator named at the end of this sheet. He will address your concerns.

Will my participation in this study be confidential?

Your general details will be collected from your hospital chart and will be entered onto the study database. This information will be stored anonymously and securely by the researchers. During the course of the trial authorised personnel may review your medical chart and collected data to assist with the research study all of them have a duty of confidentiality to you as a research participant.

What will happen to any blood samples I give?

The analysis of blood samples will be carried out at the National Centre for Biomedical Engineering Galway (NCBES), Clinical Science Institution, National University of Ireland Galway and the Centre for Clinical Investigations, University of Dijon, France. Blood samples will be stored for bio-banking and for possible future research by Professor Morrison subject to future approval from the Ethics Committee.

What will happen to the results of the research study?

The aim would be to publish the results of the trial in relevant medical journals and if necessary present the results at suitable medical meetings. At no time will you be identified in any report or publication.

Who has reviewed the study?

This study has been reviewed by the Galway Regional Hospitals Research Ethics Committee.

A copy of this information sheet and consent form will be given to the patient to keep and a copy will be kept in the patients file.

For additional information now or in the future please contact:

Principal Investigator's Name: Professor John Morrison

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Clinical Research Nurse:

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