Guy's and St Thomas' NHS
NHS Foundation Trust

EQUIPP: *Evaluation of Fetal Fibronectin with a Quantitative Instrument for the Prediction of Preterm birth (Rapid fFN 10Q)*

Participation Information Leaflet

1. Study Title

Evaluation of Fetal Fibronectin with a Quantitative Instrument for the Prediction of Preterm birth (Rapid fFN 10Q)

2. Invitation Paragraph

You have been asked to take part because you are having a fetal fibronectin swab. Fetal fibronectin is a substance normally found in pregnancy that is present between the membranes around the baby and womb and should not be present in the vagina. This indicates how the wall of the uterus is functioning through the pregnancy. We would like your help in making the fetal fibronectin test even better. After testing your sample in the usual way, we would also like to use it on a new machine to obtain a more precise result. Please read the following information. Ask us if there is anything that is not clear. You do not have to take part.

3. What is the purpose of the study?

Current fibronectin tests give either a positive or negative result. We know that a negative fibronectin test is usually very reassuring and most women with this will not deliver early. However a positive test result means a preterm birth is more likely. The new machine will tell us a level of fibronectin. At the moment we don't know if very high levels make early birth more likely then lower levels.

4. What will happen to me if I take part?

You will have the fetal fibronectin test taken in the usual way and will be given the result of the Positive/Negative test.

5. What do I have to do?

All you have to do is allow us to analyse the fibronectin swab taken from you using two different machines, instead of one. Later, the hospital team will collect information from your hospital notes about your baby's birth. This information will help us to work out the relationship between fibronectin levels and preterm birth.

6. What are the other possible disadvantages and risks of taking part?

None.

7. What are the potential benefits of taking part?

None for you, but you may help future mothers at risk of early birth.

8. What if there is a problem?

Any complaint about the research will be dealt with. Please speak to any of the researchers or midwives/doctors looking after you. If you remain unhappy and wish to complain formally, you can do this through the NHS complaints procedure.

9. Will my taking part in the study be kept confidential?

Yes. All the information about your participation in the study will be kept confidential. The data will be stored following NHS guidelines for 25 years.

10.What will happen if I don't want to carry on with the study?
Once you have agreed to have the swab analysed twice, that is the end of your participation in the study. We would still like to get information about your baby's birth from your notes and the hospital computer system.

11.What will happen to any samples I give?
The fibronectin test will be done using the vaginal swab. The swab will be destroyed afterwards.

12.What will happen to the results of the research study?
The results of the study will be published in a medical journal. You will not be identified in any report/publication.

13.Who is funding the research?
The research is being funded by Hologic USA, and the Maternal and Fetal Research Unit.

14.Who has reviewed the study?
This study was reviewed by the South West London REC4 (PRSC) Research Ethics Proportionate Review Sub-Committee.

15.Who should I contact?
If you are interested in taking part in EQUIPP or would like further information, please contact: .....(Local Contact Details)

Thank you for taking time to read this.