Appendix 2. Participant Information Sheet

Study Title: A randomised clinical trial of intrapartum fetal monitoring with computer analysis and alerts versus previously available monitoring

Invitation Paragraph:
We would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it will involve for you. Please take time to read the following carefully and discuss it with others if you wish. Part 1 tells you the purpose of this study and what will happen to you if you take part. Part 2 gives you detailed information about the conduct of the study.

If you would like any further information, or if anything is not clear, please ask us. Take time to decide whether or not you wish to take part

Part 1

What is the purpose of the study?
Doctors and midwives use the heart rate monitor (cardiotocograph, CTG) to identify the babies that may not be coping well with labour. However, interpretation of the CTG is subjective and varies widely between clinicians. Moreover, 50% of abnormal CTG patterns are not associated with any problems. To confirm this, doctors will usually do a small blood test (fetal blood sampling FBS) on the baby's head, or directly monitor the electrical signals from the baby's heart (ST analysis, (STAN)). However, FBS is invasive, time consuming, and only provides time-limited information whilst human errors continue to limit the utility of STAN monitoring.

Recently, a new computerised method of analysis of fetal monitoring signals (Omniview-SisPorto® 3.5) with real-time alerts for healthcare professionals has been developed. Since computer analysis may reduce human errors, we plan to test whether these alerts will help doctors and midwives to reduce the number of babies affected by lack of oxygen during labour, compared to those monitored in the usual way. This will make no difference to your normal care or that of your baby, and we invite you to participate in this study.

Why have I been invited?
You will be invited to participate if you are pregnant with just the one baby, up to and over 36 completed weeks of gestation, and when a clinical decision has been made to monitor your baby continuously with CTG or STAN during labour. We aim to study a total of 8,133 women from four maternity units in the United Kingdom.

Do I have to take part?
It is up to you to decide whether or not to take part. If you do, you will be given this information sheet to keep and asked to sign a consent form. You are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time or not take part will not affect the standard of care you receive.

What will happen to me if I take part?
Participation in the study is limited to the period that you are in labour. If a clinical decision is made to monitor your baby continuously during labour, you would be eligible to participate. If you agree to participate, you would be randomly allocated to one of two groups. In one group the baby's heart signals are analysed by the new computerised method (Omniview-SisPorto® 3.5) and any alerts are displayed on a computer screen for the doctors and midwives to analyse and act on. Women in the other half of the participants are monitored in the same way, but

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The authors provided this information as a supplement to their article.

there will not be the extra computerised analysis and alerts for doctors and midwifes. It is not possible to know ahead of the random allocation, which group individual participants will be allocated to. After delivery, the blood in the baby's placenta, which is usually discarded, is tested to determine the level of oxygen. The doctors and midwives doing the study will obtain the relevant information on your pregnancy, labour and delivery including information on your baby from your clinical records.

What do I have to do?
The study does not involve any additional hospital visits or intake of medications. You may still participate if you have been involved in other studies, provided that those other studies are not also during your labour.

What is the device being tested?
The device being tested is the Omniview-SisPorto® 3.5 system (Speculum, Lisbon, Portugal), which provides computer analysis of both CTG and ST signals. It also features centralised viewing of tracings on multiple posts and online alerts for healthcare professionals. The system has already been shown to provide analysis of CTG events that is in good agreement with that of experts, and the program's online alerts have also been shown to be highly predictive of babies born with severe oxygen deprivation.

What are the disadvantages and risks of taking part?
The signals obtained from the baby's heart during labour are obtained in the usual way. Therefore, there are no additional risks, discomfort or inconvenience over and above those experienced by women having continuous electronic fetal monitoring as a result of participation in the study.

What are the side-effects of any treatment received when taking part?
Not applicable.

What are the possible benefits of taking part?
We believe that computer analysis of fetal monitoring signals can reduce the frequency of human errors associated with CTG interpretation and that online alerts may prompt healthcare professionals to act in a more timely fashion to changes that are detected in these signals. This can be a potential advantage for part of the study participants.

What happens when the research study stops?
At the end of the study, the results will be analysed and participants who are interested in the outcome will be sent a summary of our findings.

What if there is a problem?
Any complaint about the way you have been dealt with or any possible harm you might suffer will be addressed. The detailed information on this is given in part 2

Will my taking part in the study be kept confidential?
Yes, all the information about your participation in this study will be kept confidential. The details are in part 2.

This completes Part 1.
If the information in Part 1 has interested you and you are considering participation, please read the additional information in part 2 before making any decision.

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Part 2

What if relevant new information becomes available?
Sometimes we get new information about the treatment or medical device being studied. If this happens your research doctor will tell you and discuss whether you should continue in the study. If you decide not to carry on, your research doctor will make arrangements for your care to continue. If you decide to continue in the study he/she may ask you to sign an updated consent form. If the study is stopped for any other reason, we will tell you and arrange your continuing care.

What will happen if I don't want to carry on with this study?
You can withdraw from the study at any time and without giving any reason for your withdrawal. However, information collected may still be used. Any stored blood or tissue samples that can still be identified as yours will be destroyed if you wish.

What if there is a problem?
If you have a concern about any aspect of this study you should ask to speak with the researchers who will do their best to answer your questions. If you remain unhappy and wish to complain formally you can do this through the NHS Complaints Procedure (or private institution). Details can be obtained from the hospital

Will my taking part in the study be kept confidential?
Yes. Your confidentiality will be safeguarded during and after the study. Your basic demographic and clinical data will be abstracted from your clinical records and stored securely in a coded way. This information will be used to analyse the results of the present study. We also plan to retain the data for use in future studies, and will always seek further Research Ethics Committee approval for such a future study.

We are generally informing all local GPs in the area of the study, but there are no plans to specifically inform your GP of your participation or seek his/her consent.

What will happen to any samples I give?
Immediately after delivery, the blood in the stump of the umbilical cord attached to the baby's placenta is tested to determine the level of oxygen in the blood. The sample is discarded after the test and not retained.

Will any genetic tests be done?
No.

What will happen to the results of the research study?
We intend to publish the results of the study in a medical journal, with the overall findings made available to participants. No participant will be identified in any report or publication unless they have given specific consent for this.

Who is organising and funding the research?
The study is funded by the University of Porto in Portugal, the Portuguese Innovation Agency and Speculum, Lisbon, the manufacturers of Omniview-SisPorto® 3.5 program.

Who has reviewed the study?
All research in the NHS is looked at by an independent group of people called a Research Ethics Committee to protect your safety, wellbeing and dignity. This study has been reviewed and given a favourable opinion by Cambridgeshire 1 Research Ethics Committee.

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