PARTICIPANT CONSENT FORM

Study title: *Fetal Scalp Stimulation (FSS) versus Fetal Blood Sampling (FBS) to assess fetal wellbeing in labour – a multi-centre randomised controlled trial.*

Please initial the boxes

I have read and understood the **Information Leaflet** about this study. The information has been fully explained to me and I have been able to ask questions, all of which have been answered to my satisfaction.	**Yes**	**No**
I understand that I don't have to take part in this study and that I can withdraw at any time. I understand that I don't have to give a reason for my withdrawal, and it won't affect my future medical care.	**Yes**	**No**
I am aware of the potential risks, benefits and alternatives of this research study and consent to take part in the research.	**Yes**	**No**
I give permission for members of the research team in the Coombe and TCD to look at my medical records to get information for this study. I have been assured that information about me will be kept private and confidential.	**Yes**	**No**
I give permission for the Ethics Committee and any other representatives of the Sponsor, or any regulatory authorities etc. to look at my baby's and my medical notes to allow them to check that the study has been run safely.	**Yes**	**No**
I understand that the sponsor and Investigators have such insurance as is required by law in the event of injury resulting from this research.	**Yes**	**No**
I have been given a copy of the Information Leaflet and this completed consent form for my records.	**Yes**	**No**
I consent to take part in this research study having been fully informed of the risks, benefits and alternatives.	**Yes**	**No**
I give informed explicit consent to have my data and my baby's data processed as part of this research study.	**Yes**	**No**
I understand if I have any further questions, I can contact the Study Doctor listed below.	**Yes**	**No**
I confirm that I have read and understood the UCC Data Protection Notice that accompanied the Participant Information Leaflet	**Yes**	**No**

FUTURE CONTACT		
I consent to be re-contacted by researchers about possible future research **related** to the current study for which I may be eligible.	**Yes**	**No**

STORAGE AND FUTURE USE OF INFORMATION		
I give permission for data to be stored for *possible future research* ***related*** to the current study (fetal wellbeing in labour) ***without further consent being required*** but only if the research is approved by a Research Ethics Committee.	**Yes**	**No**

Name of Participant: _____

(Block Capitals)

Signature of Participant: _____Date: _____ Time(24hr)_____

To be completed by the Principal Investigator/Co-Investigator obtaining consent.

I, the undersigned, have taken the time to fully explain to the above patient the nature and purpose of this study in a way that they could understand. I have explained the risks involved as well as the possible benefits. I have invited them to ask questions on any aspect of the study that concerned them.

Name (Block Capitals) _____Qualification: _____

Signature: _____ Date: _____ Time(24hr)_____

3 copies to be made: 1 for participant, 1 for Study File and 1 for hospital medical records.