To be printed on Local Trust Headed Paper

SOLVE Consent Form

SOLVE Trial Number:

The participant must initial each box to confirm consent & enter date/version of information sheet

A randomised controlled trial of a Synthetic Osmotic cervical dilator for induction of Labour in comparison to dinoprostone Vaginal insErt

I confirm that I have read and understood the information sheet dated __/__/____ version ___(please complete) for the above study. I have had the opportunity to consider the information, ask questions and these have been answered satisfactorily.	☐
I understand that my participation is voluntary and that, if I take part, I am free to withdraw at any time without giving a reason and without my medical care or legal rights being affected. However I am aware that, once induction has started, it may not be possible to stop or change the method of induction.	☐
I understand that my doctors will provide a copy of my consent form and personal information about my and my baby's progress, in confidence, to the central organisers at Birmingham Clinical Trials Unit (BCTU), University of Birmingham for use in the SOLVE trial. I understand that the information held by the NHS may be used to keep in touch with me and follow up my and my baby's health status.	☐
Data collected that identifies me by name (on the consent form), will be transferred from where it is collected and stored to the University of Birmingham. I agree to the transfer and storage of this data.	☐
I understand that the information collected will be used for medical research only and that I will not be identified in any way in the analysis and reporting of the results. I understand that relevant sections of my/my baby's medical notes and data collected during the study may be looked at by individuals from the University of Birmingham, regulatory authorities, sponsor or the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	☐
I understand that if I am randomly allocated to the Dilapan-S group and there is a problem with the device, my anonymised data will be sent to the central organisers at Birmingham Clinical Trials Unit (BCTU), University of Birmingham and they will send this information to the manufacturer of Dilapan-S (Medicem). This process is part of the manufacturer's safety monitoring of Dilapan-S.	☐
I understand what is involved in the SOLVE Trial and agree to participate.	☐
I agree to my GP being informed of my participation in the SOLVE trial.	☐

Name of Participant	Date	Signature
Name of Person taking consent	Date	Signature

I have interpreted the information above to the best of my ability and in a way in which the patient can understand (if applicable).

Name of Interpreter	Date	Signature

When complete: Original copy for site file, 1 copy for patient, 1 copy for patient's hospital notes and 1 copy faxed to Trial Office on 0121 415 9136