LOCAL HOSPITAL HEADER

PRISM: PROGESTERONE IN EARLY PREGNANCY BLEEDING

PARTICIPANT CONSENT FORM

Please initial:

I confirm that I have read and understand the participant information sheet (version 3.0, 16-Nov-2016) for the PRISM Trial. I have had the opportunity to ask questions and these have been answered satisfactorily.	
I understand that my participation in the trial is voluntary and I am free to withdraw at any time without my treatment or legal rights being affected.	
I understand that my local research team will provide a copy of my consent form and personal information about my progress, in confidence to the study organisers at the University of Birmingham for use in the PRISM Trial.	
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 even if I withdraw from the study, information already collected about me may be included in the final study analysis after being anonymised.	
I understand that relevant sections of my medical notes and my baby's medical notes and data collected during the study may be looked at by members of the research team or the NHS Trust of my participating study centre, or by individuals from statutory regulators. I give permission for these individuals to have access to my records.	
I understand that the information held by the NHS may be used to keep in touch with me and follow up my pregnancy status for the purposes of the study.	
I understand that researchers for the PRISM Trial based at my hospital or at the University of Birmingham may contact me by telephone, mobile telephone, post or e-mail to request information.	
I understand that researchers may want information about my baby's development or my condition in the future. I understand I may be contacted in the future to give my consent for future studies, and that I may be traced through the NHS databases and GP records.	
I agree for my General Practitioner to be informed about my participation in the study.	
I understand the information that I have been given about the PRISM Trial and I agree to take part.	

Name of Participant: _____ Date: _____ Signature: _____

Name of Researcher: _____ Date: _____ Signature: _____

Participant Study Number:

(please complete when participant is randomised)

Top copy for Site File, 1 copy for Participant, 1 copy for PRISM Trial Office

LOCAL HOSPITAL HEADER

GP NAME

PRACTICE NAME

PRACTICE ADDRESS

DATE

Dear Dr GP NAME,

Re: Progesterone In Early Pregnancy Bleeding (PRISM) Trial

Name	
DOB	
Address	

Your patient has kindly agreed to take part in the PRISM Study - a multi-centre, randomised-controlled, blinded study of progesterone capsules versus placebo for the prevention of miscarriage. This study is funded by a Health Technology Assessment award from the National Institute of Health Research and granted regulatory approval by the South Central- Oxford C Research Ethics Committee.

Your patient will be randomised to either the Intervention Group, taking 400 mg (2 x 200 mg) progesterone twice daily, or the Non-Intervention Group, taking placebo. The study drugs will be inserted vaginally or rectally. Since this is a double blind study, neither the participant nor our study investigators will know the treatment allocation of your patient. Your patient has the contact details of our research team members in case of any difficulties.

We do not anticipate that the participation of your patient in our study will affect your care for her, and we will not ask you to carry out any study-related investigations or interventions.

This letter is for information only.

If you would like any further details, please feel free to contact our Trial Co-ordinator via prism@trials.bham.ac.uk or 0121 623 6835.

Thank you for your support.

Yours sincerely,

LOCAL PRINCIPAL INVESTIGATOR