MifeMiso

Mifepristone and misoprostol versus misoprostol alone in the medical management of missed miscarriage: the MifeMiso randomised controlled trial

Appendix II: Participant Consent Form

LOCAL HOSPITAL HEADER

Participant trial number:
please complete when patient is randomised

MifeMiso: A randomised placebo-controlled trial of mifepristone and misoprostol versus misoprostol alone in the medical management of missed miscarriage

PARTICIPANT CONSENT FORM

Chief Investigator: Professor Arri Coomarasamy

Initial each box to confirm consent

I confirm that I have read and understand the patient information leaflet (version _._, dated _ _ / _ _ _ / _ _ _ _) for the MifeMiso 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, which identifies me by name, and personal information about my progress, in confidence, to the study organisers at the University of Birmingham where my data will be stored for use in the MifeMiso Trial. 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 an external database provider will be used to securely store information about me. 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 data collected during the study may be looked at by individuals from the research team, representatives of the sponsor, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have direct 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 status for the purposes of the study.	
I understand that researchers for the MifeMiso 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 I may be contacted to ask if I am willing to undertake a face-to-face interview with a researcher from the University of Birmingham to discuss my experiences of taking part in the trial.	
I consent to being contacted in the future to ask for my consent to future studies, and that I may be traced through the NHS databases and GP records. **Yes** ☐ **No** ☐	
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 MifeMiso Trial and I agree to take part.	

Name of Participant: _____ **Date:** _____ **Signature:** _____

Name of Researcher: _____ **Date:** _____ **Signature:** _____

For the translator (if required):
I confirm that I have interpreted the study information to the best of my ability and ensured the patient fully understands everything that has been given to them to read/verbally explained to them

Name of translator: _____ **Date:** _____ **Signature:** _____

Master copy for Site File, 1 copy for participant notes, 1 copy for Participant, 1 copy for MifeMiso Trial Office