

Consent Form

Please complete in black ballpoint pen

Phase III trial in IntrahepaTic CHolestasis of pregnancy (ICP) to Evaluate urSodeoxycholic acid (UDCA) in improving perinatal outcomes		
Hospital Name:		
Chief Investigator: Dr Lucy Chappell		
Study	Number:	Please initial box
1.	I confirm that I have read and understand the Pa dated 12Feb15) for this study and have had the been answered satisfactorily.	
2.	I understand that participation in this study is voluntary and that I am free to withdraw from the study at any time without giving any reason, and without my present or future medical care or legal rights being affected.	
3.	I understand that relevant sections of medical records and data collected during the study may be looked at by the study coordinating centre in Oxford, the co-sponsors, or this NHS Trust. I give permission for these individuals to have access to these records where it is relevant to taking part in this research.	
4.	I understand that information held and managed by the Health and Social Care Information Centre and other central UK NHS bodies will be used in order to help contact me or provide information about my health status, and that of my baby. This is on the understanding that all information will be treated confidentially.	
5.	I agree that personal identifiable information will be collected, stored and used to follow my progress through the study and enable follow-up. This is on the understanding that all information will be treated confidentially.	
6.	6. I agree to my GP being informed of my participation in the study.	
7.	I agree to take part in the study.	
Nam	e of participant	Name of health professional taking consent
Sign	ature	Signature
DD/MM/YY DD/MM/YY		
PITCHES Trial NPEU Clinical Trials Unit, National Perinatal Epidemiology Unit Nuffield Department of Population Health, University of Oxford Old Road Campus, Oxford, OX3 7LF T: 01865 289735 F: 01865 289740 E: pitches@npeu.ox.ac.uk W: www.npeu.ox.ac.uk/pitches EudraCT Number 2014-004478-41, ISRCTN 91918806, REC Reference 15/EE/0010 Version 2, 12 February 2015		

WHITE copy to PITCHES Coordinating Centre; GREEN copy to participant; YELLOW copy to PITCHES Data Collection File; PINK copy to participant's notes