Trust Header and logo

When to Induce Labour to Limit risk in pregnancy hypertension –

a multicentre, randomised controlled trial

WILL

Site name: **Principal Investigator:**

Last four digits of woman's NHS number: ☐☐☐☐

Woman's Month and Year of birth: M M N / Y Y

Please ask the woman to read then initial inside each box

	Participant Trial number: ☐☐☐☐	
1	I confirm that I have read and understood the information sheet, version number #.# dated _ _ / _ _ / _ _ _ _ for the **WILL** Study. I have had the opportunity to consider the information, ask questions, and have had these answered satisfactorily.	*Initials*
2	I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my medical care or legal rights of me of my baby being affected.	*Initials*
3	I agree that the study researchers may contact me by post, text, email or telephone to remind me to complete the questionnaire and find out how I am doing prior to delivering my baby and how I and my baby are doing after my discharge home.	*Initials*
4	I understand that relevant sections of my and my baby's medical notes, and data about me and my baby collected during the study and from central government databases may be looked at by individuals from King's College London, Guy's and St Thomas' NHS Foundation Trust and Birmingham CTU, the regulatory authorities or the NHS Trust, where this is relevant to me and my baby taking part in this research. I give permission for these individuals to have direct access to my and my baby's records.	*Initials*
5	I agree that the research team can link data collected about me and my baby from the study or our health records with other routinely-collected health, educational, or social data, in order to learn more about the impact of different planned timing of delivery for women with high blood pressure in a term pregnancy.	*Initials*
6	I agree to my GP Practice being informed of my participation in this study. I agree that my GP may be contacted by the study researchers to obtain information about any health problem I or my baby may have after I leave hospital.	*Initials*
7	Personal data collected that identifies me by e.g. name, address, telephone number, date of birth will be transferred from where it is collected and sent to the University of Birmingham where it will be stored in a secure place. I agree to the confidential transfer and storage of these data.	*Initials*
8	I understand that all information collected on me and my baby for this study will be subject to the General Data Protection Regulation and Data Protection Act 2018. This	*Initials*

	Participant Trial number: ☐☐☐☐	
	information will be stored securely at the University of Birmingham. Guys' and St Thomas' NHS Foundation Trust and King's College London is are acting as the Data Controllers for the WILL study.	
9	I understand that I can withdraw my consent for the data about me and my baby to be processed at any time. I understand that should I ask that information about me or my baby is not used then no new research will be started using data about me or my baby.	*Initials*
10	I agree that anonymised data collected about me or my baby may be shared with other Universities, NHS Organisations, or other companies involved in healthcare research, and this may be in the UK or abroad. I understand that if anonymised data about me or my baby is transferred then neither I nor my baby will be identified in any way and the data will only be used for health research and no other purpose.	*Initials*
11	I agree to my study number and mobile telephone number being passed to a private company (Textlocal) who will send me text messages to follow-up how my baby and I are doing six weeks after my discharge home. I understand that my study number, telephone number and responses will be encrypted whilst being stored by Textlocal and my data will not be used by them for any other purpose. Once my responses have been transferred from Textlocal to the study database held at the University of Birmingham I understand that Textlocal will securely delete all of my and my baby's data that they hold.	*Initials*
12	I understand what is involved in the WILL study and I agree to take part.	*Initials*
13	**Optional**: I agree that the members of the study team may contact me in the future by post, email, telephone, or text to learn how I am doing and how my child is developing. This will be for the purpose of helping healthcare staff and researchers see if the different timing of delivery has any long-term effects on children's development. I understand that if I agree to be contacted in the future it does not mean that I have to take part in any future studies, and that the researchers involved in any future work will not access any information about me or my baby without my written permission.	*Initials*

Print Name of Woman	*Date (dd-mon-yy)*	*Woman's Signature*
Name of Person taking Consent	*Date (dd-mon-yy)*	*Signature of Person taking Consent* |

If the woman was consented remotely, how was consent taken? *Please mark ONE only*

Remote consent: Woman signed ☐ Remote consent: Research Staff signed on woman's behalf ☐

Witness Details (if remote consent takes place and the woman is not able to sign for herself)

Name of Witness	*Date (dd-mon-yy)*	*Signature of Witness*

When completed and signed **please make THREE copies of this form** and please: **Give one copy to the woman; Place one copy in the Investigator Site File; Return one copy to the WILL study office at Birmingham Clinical Trials Unit; and place this signed original in the woman's Maternity Notes.**