



1 - SCREENING, CONSENT and KEY BASELINE INFORMATION FORM

This form should be completed for **ALL WOMEN CONSIDERED FOR PARTICIPATION IN THE WILL TRIAL.**

Section 1 - Woman's details

1.1 Study number (computer-generated) <input style="width: 30px; height: 20px; border: 1px solid red;" type="text"/> <input style="width: 30px; height: 20px; border: 1px solid red;" type="text"/> <input style="width: 30px; height: 20px; border: 1px solid red;" type="text"/> <input style="width: 30px; height: 20px; border: 1px solid red;" type="text"/>	1.2 Last 4 digits of woman's NHS number <input style="width: 20px; height: 20px; border: 1px solid red;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid red;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid red;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid red;" type="text"/>
1.3 Woman's DOB e.g. JAN2017 <input style="width: 20px; height: 20px; border: 1px solid red;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid red;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid red;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid red;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid red;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid red;" type="text"/>	1.4 Hospital name: _____
1.5 Date of screening : <input style="width: 20px; height: 20px; border: 1px solid red;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid red;" type="text"/> - <input style="width: 20px; height: 20px; border: 1px solid red;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid red;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid red;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid red;" type="text"/> - <input style="width: 20px; height: 20px; border: 1px solid red;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid red;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid red;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid red;" type="text"/>	

Section 2 - Inclusion checklist

2.1 Maternal age 16 years or more?	<input type="radio"/> No <input type="radio"/> Yes						
2.2 Diagnosis of chronic or gestational hypertension?	<input type="radio"/> No <input type="radio"/> Yes						
2.3 Singleton pregnancy?	<input type="radio"/> No <input type="radio"/> Yes						
2.4 Live fetus?	<input type="radio"/> No <input type="radio"/> Yes						
2.5 Method of gestational age estimation <i>Please mark ONE only.</i>	<input type="radio"/> Ultrasound <input type="radio"/> Last menstrual period (LMP) only						
2.6 Please indicate Estimated Date of Delivery (EDD): <input style="width: 20px; height: 20px; border: 1px solid red;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid red;" type="text"/> - <input style="width: 20px; height: 20px; border: 1px solid red;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid red;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid red;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid red;" type="text"/>							
What is the woman's gestational age at screening?	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 25%; padding: 2px;">Weeks</td> <td style="width: 25%; padding: 2px;">Days <i>(This must be 0 - 6)</i></td> <td style="width: 50%; padding: 2px;">Not applicable, previously screened and now post-partum.</td> </tr> <tr> <td style="padding: 2px;"><input style="width: 20px; height: 20px; border: 1px solid red;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid red;" type="text"/></td> <td style="padding: 2px;"><input style="width: 20px; height: 20px; border: 1px solid red;" type="text"/></td> <td style="padding: 2px;"><input style="width: 20px; height: 20px; border: 1px solid red;" type="text"/></td> </tr> </table>	Weeks	Days <i>(This must be 0 - 6)</i>	Not applicable, previously screened and now post-partum.	<input style="width: 20px; height: 20px; border: 1px solid red;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid red;" type="text"/>	<input style="width: 20px; height: 20px; border: 1px solid red;" type="text"/>	<input style="width: 20px; height: 20px; border: 1px solid red;" type="text"/>
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2.7 Gestational age of 36+0 to 37+6 weeks? <i>(At screening date)</i>	<input type="radio"/> No <input type="radio"/> Yes						
2.8 Able to give documented informed consent to participate?	<input type="radio"/> No <input type="radio"/> Yes						

Section 3 - Exclusion checklist

NOTE: Neither maternal co-morbidities (e.g. diabetes) nor fetal size are exclusion criteria.

3.1 Contraindication to either one of the trial arms?	<input type="radio"/> No <input type="radio"/> Yes								
3.1.1 If yes , please specify contraindication(s) to either one of the trial arms. <i>Please tick ALL that apply.</i>									
<input type="radio"/> Evidence of pre-eclampsia <input type="radio"/> Other									
3.1.2 If other , please specify from the list. REMEMBER that these conditions are NOT contraindications for all women but may reflect legitimate reasons why <u>this</u> woman may not be suitable for WILL: <i>Please tick ALL that apply.</i>									
<table style="width: 100%;"> <tr> <td style="width: 50%;"><input type="radio"/> GDM with poor glycaemic control</td> <td style="width: 50%;"><input type="radio"/> GDM on insulin</td> </tr> <tr> <td><input type="radio"/> GDM on an oral hypoglycaemic agent</td> <td><input type="radio"/> Planned elective Caesarean</td> </tr> <tr> <td><input type="radio"/> Chronic kidney disease</td> <td><input type="radio"/> Obesity (BMI $\geq 30\text{kg/m}^2$)</td> </tr> <tr> <td><input type="radio"/> Care provider does not want woman to participate</td> <td><input type="radio"/> Other</td> </tr> </table>		<input type="radio"/> GDM with poor glycaemic control	<input type="radio"/> GDM on insulin	<input type="radio"/> GDM on an oral hypoglycaemic agent	<input type="radio"/> Planned elective Caesarean	<input type="radio"/> Chronic kidney disease	<input type="radio"/> Obesity (BMI $\geq 30\text{kg/m}^2$)	<input type="radio"/> Care provider does not want woman to participate	<input type="radio"/> Other
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If **other** please specify:

Please confirm all above items have been considered and that only those ticked apply.

No Yes

3.2 Severe hypertension (i.e., BP \geq 160mmHg systolic or \geq 110mmHg diastolic)? (until BP is below this level; i.e., is 'controlled')

No Yes

3.3 Major fetal anomaly anticipated to require neonatal unit admission?

No Yes

3.4 Participation in another timing of delivery trial?

No Yes

NOTE: if **ANY of the shaded boxes** in Sections 2 and 3 above are ticked, then the woman is **ineligible** to take part in WILL. If that is the case, please go to **Section 4**.

If **NONE of the shaded boxes** in Sections 2 and 3 above are ticked, then the woman is **eligible** to take part in WILL. Please share the *Participant Information Sheet* with the woman, and proceed to **Section 5**.

6.4 Most recent BP before consent: Systolic (should be ≤ 159 mmHg) Diastolic (should be ≤ 109 mmHg)

How was this BP taken? Please mark ONE only. Automated device (any type) Aneroid device (manual) Don't know

6.5 Is the woman currently using home BP monitoring? No Yes

6.6 Previous Caesarean delivery? No Yes

If the woman is 36+0 to 36+6 weeks, please complete Section 7 recontact her when she is 37+0 to 37+6 weeks to reconfirm eligibility and randomise her if eligible.

If the woman is 37+0 to 37+6 weeks, please complete Section 7 and then Form 2 - RECONFIRMATION OF ELIGIBILITY & RANDOMISATION FORM.

Section 7 - Form completion details

Name of person completing form:

Date of form completion : - -