2 - RECONFIRMATION OF ELIGIBILITY & RANDOMISATION FORM

This form should be completed for **ALL WOMEN WHO HAVE CONSENTED TO PARTICIPATE IN THE WILL TRIAL**

Section 1 - Woman's details

1.1 Woman's study number ☐☐☐☐	1.2 Last 4 digits of mother's NHS number N N N N
1.3 Woman's DOB M M M Y Y Y Y	1.4 Hospital name: _____

Section 2 - Reconfirmation of eligibility prior to randomisation *(for women who have consented)*

2.1 What is the woman's gestational age?

- ◯ 37+0-37+6 weeks *(This woman may be eligible to be randomised. Please proceed to Q2.2.)*
- ◯ 38+0 weeks or more *(This woman can no longer be randomised. Please proceed to **Section 4**.)*
- ◯ Not applicable as this woman has given birth *(This woman can no longer be randomised. Please proceed to **Section 4**.)*

2.2 Was the woman consented today?

- ◯ No *(Please proceed to Q2.3 to Q2.5 to reconfirm eligibility.)*
- ◯ Yes *(Please proceed to **Section 3** for randomisation.)*

2.3 Have any new plans been made for timing of birth that would prevent the woman being randomised to either arm? ◯ No ◯ Yes

If yes, this woman can no longer be randomised. Please proceed to Section 4

2.4 Has the woman had any of the following **symptoms of pre-eclampsia** since she consented to participate in WILL *or if more recently*, she was contacted to reconfirm eligibility? *Please mark no or yes to **EACH** question.*

New headache (severe)?	◯ No	◯ Yes
New visual scotomata (persistent)?	◯ No	◯ Yes
New right upper quadrant abdominal or epigastric pain?	◯ No	◯ Yes
Any decrease or change in the pattern of fetal movements?	◯ No	◯ Yes

If yes to **ANY of shaded boxes**, advise the woman to contact her midwife or hospital doctor to be reassessed, then proceed to **Section 4**. Arrange to recontact the woman after she has liaised with her midwife or hospital doctor.

If **ALL responses are no**, please proceed to question 2.5.

2.5 Is the woman using home BP monitoring? ◯ No *(Please proceed to Q2.6.)* ◯ Yes

If yes , is her BP acceptable according to criteria set by her hospital doctor? ◯ No ◯ Yes ◯ Don't know

If no, please advise the woman to contact her midwife or hospital doctor to be reassessed, then proceed to **Section 4**. Arrange to recontact the woman after she has liaised with her midwife or hospital doctor.

If **yes** or **don't know**, please proceed to **Q2.6**.

2.6 Is the woman still willing to be randomised? *Consent MUST be verbally reaffirmed as informed consent was taken on a different day.*

- ◯ No *(Please go to **Section 4** and then complete a **'11 - Trial Withdrawal Form'**.)*
- ◯ Yes *(Please go to **Section 3** for randomisation.)*

(Please proceed to next page.)

Section 3 - Randomisation

In order to randomise the woman, you will need ALL of the following information:

The information below is based on answers to questions on Form 1 (with the specific questions indicated in brackets for your reference).

Please check the information. If it is not correct, please contact the randomisation line at 0800 953 0274 (available Monday to Friday 0:900-17:00).

Did the woman give documented informed consent to take part in the WILL trial? *(From Form 1, Q5.1)* ◯ No ◯ Yes

If **yes**, date of consent *(From Form 1, Q5.1)* D D - M M M - Y Y Y Y | Consent Form Version *(From Form 1, Q5.1)* __ . __

Type of hypertension *(From Form 1, Q6.1)* ◯ Chronic ◯ Gestational

Previous Caesarean delivery? *(From Form 1, Q6.6)* ◯ No ◯ Yes

When you have answered all the questions in 'Section 3 – Randomisation' above, use the online randomisation service **https://www.trials.bham.ac.uk/WILL** and enter the details to obtain the group allocation.

If you have any difficulties, please call the randomisation line at 0800 953 0274 (available Monday to Friday 09:00-17:00hrs).

Please find below the group allocation *(as per the ticked box, or if randomised by telephone, please tick group allocation)*

◯ **Early term delivery at 38+0 to 38+3 weeks**

◯ **Expectant care at term until at least 40+0 weeks**

Following randomisation, please answer the following questions.

3.1 Name of person who randomised woman: _____

3.2 Date of randomisation: D D M M M Y Y Y Y

Section 4 - Form completion details

Name of person who completed form: _____

Date of form completion: D D M M M Y Y Y Y

If the woman **declined randomisation** (as per Q2.6), please complete a **Form 11 - TRIAL WITHDRAWAL FORM**. No other forms need to be completed.

If the woman's **eligibility could not be reconfirmed today**, please arrange to recontact the woman after she has liaised with her midwife or hospital doctor. You will need to complete another '**Form 2 - RECONFORMATION OF ELIGIBILITY & RANDOMISATION FORM**' at that time.

If the woman is **randomised**, please complete a **Form 3 - ADDITIONAL BASELINE INFORMATION FORM**.

If the woman is **38+0 weeks or more**, or ineligible for another reason, she can no longer be randomised. Please complete **Form 3** and when she has given birth, **Forms 5, 6, and 7**.

If the woman **has already given birth**, she can no longer be randomised. Please complete **Forms 3, 5, 6, and 7**.

Below please find a list of the other WILL Forms for your reference.

Form 3 = Baseline

Form 4 = Maternal & Fetal Surveillance & Antenatal Care

Form 5 = Delivery

Form 6 = Maternal Outcome & Postpartum Management

Form 7 = Neonatal

Form 8 = Childbirth Experience Questionnaire

Form 9 = Six-week Postpartum

Form 10 = SAE

Form 11 = Trial Withdrawal

Form 12 = Protocol Deviation