11 - TRIAL WITHDRAWAL FORM

This form should be used for all women who withdraw from trial participation, as outlined in Section 8.4 of the WILL protocol.

Section 1 - Woman's details

1.1 Woman's study number | | | | |

1.2 Last 4 digits of woman's NHS number N N N N

1.3 Woman's DOB M M M Y Y Y Y

Section 2 - Nature of the withdrawal

2.1 What was the date of withdrawal ? *(If the woman was not randomised, please use the date on which she declined to be randomised.)*

D D M M M Y Y Y Y

2.2 What was the reason for the withdrawal? *Please mark ALL that apply.*

- ◯ No longer wished to be randomised -> *Please proceed to **Section 4**.*
- ◯ Unhappy with trial
- ◯ No reason given
- ◯ Other *(please specify below)*

Please confirm all above items have been considered and that only those ticked apply. ◯ No ◯ Yes

If **other**, please specify:

_____

2.3 Who requested that the woman be withdrawn? *Please mark ONE only.*

- ◯ Health care professional
- ◯ Woman herself
- ◯ Other *(please specify below)*

If **other**, please specify:

_____

2.4 Please provide details to help us understand why the woman withdrew:

_____

_____

_____

Section 3 - Follow-up and data collection

3.1 Was the woman randomised in WILL? ◯ No *(Please proceed to Q3.3.)* ◯ Yes *(Please proceed to Q3.2.)*

3.2 Did the woman agree to have follow-up in accordance with the Schedule of Assessments? *(i.e., weekly midwifery contacts until birth, complete the '8 - CHILDBIRTH EXPERIENCE QUESTIONNAIRE', and be contacted by text at 6 weeks postpartum to complete the postpartum questionnaire)*

◯ No ◯ Yes

3.3 Did the woman agree that the data collected so far can be used? ◯ No ◯ Yes

3.4 Did the woman agree that we can continue to collect data from her and her baby's medical records? ◯ No ◯ Yes

3.5 Did the woman agree that data about her and her baby can be collected from any central UK NHS organisations for long-term outcomes? ◯ No ◯ Yes

Section 4 - Nature of withdrawal according to the protocol

According to your responses, this woman has the following type of withdrawal according to the WILL protocol.

The type of withdrawal has been automatically assigned based on the information provided on this form.

*If you believe that the assignment is incorrect, please review the earlier responses to confirm. Otherwise, please proceed to **Section 5**.*

1. **After consent,** the woman declines to be randomised. ◯ No ◯ Yes

2. **After consent**, the woman who did not have the opportunity to be randomised (because she delivered, became ineligible, or it was not possible to randomise her prior to 38+0 weeks) has agreed that data can be collected at standard clinic visits and used in the trial analysis, including data collected to date, but she is NOT willing to have data collected from any central UK NHS bodies for long-term outcomes.
◯ No ◯ Yes

3. **After consent**, the woman who did not have the opportunity to be randomised is NOT willing to have any further data collected from medical records or any central UK NHS bodies for long-term outcomes. She has agreed that data collected prior to the withdrawal can be used in the trial analysis.
◯ No ◯ Yes

4. **After consent**, the woman who did not have the opportunity to be randomised is NOT willing to have any of her data, including those already collected, used in any future trial analysis.
◯ No ◯ Yes

5. **After randomisation**, the woman does NOT wish to have follow-up in accordance with the Schedule of Assessments (i.e., receive weekly contact from randomisation until birth from the research midwife, complete the Childbirth Experience Questionnaire, and/or complete the 6-week postpartum questionnaire sent by text message), but she has agreed that data can be collected at standard clinic visits and used in the trial analysis, including data collected to date and those from any central UK NHS bodies for long-term outcomes.
◯ No ◯ Yes

6. **After randomisation**, the woman does NOT wish to have follow-up in accordance with the Schedule of Assessments (i.e., receive weekly contact from randomisation until birth from the research midwife, complete the Childbirth Experience Questionnaire, and/or complete the 6-week postpartum questionnaire sent by text message). She has agreed that data can be collected at standard clinic visits and used in the trial analysis, including data collected to date; however, she has NOT agreed to use of data from any central UK NHS bodies for long-term outcomes.
◯ No ◯ Yes

7. **After randomisation**, the woman is NOT willing to either be followed up in any way for the purposes of the trial, or have any further data collected from medical records or any central UK NHS bodies for long-term outcomes. She has agreed that data collected prior to the withdrawal can be used in the trial analysis.
◯ No ◯ Yes

8. **After randomisation**, the woman would like to withdraw completely from all follow-up. She is NOT willing to have any of her data, including those already collected, used in any future trial analysis.
◯ No ◯ Yes

Section 5 - Form completion details

Name of person completing form:	Date of form completion D D M M M Y Y Y Y