10 - SERIOUS ADVERSE EVENT (SAE) FORM

This form should be completed for **ALL WOMEN WHO WERE CONSENTED AND RANDOMISED IN THE WILL TRIAL**

(Do not complete this form for women who were NOT randomised.)

This form should be completed for any **expeditable SAEs** (as per the WILL Protocol, Section 9.3.2) occurring from randomisation until 6 weeks postpartum.

This form is NOT required for protocol-exempt SAEs which are either: (i) SAEs that are expected as a consequence of the high-risk nature of the patient population enrolled in WILL (and are therefore captured on the CRFs), or (ii) SAE's unrelated to the intervention but due instead to the woman's routine care (WILL protocol, Section 9.3.1). These events should still be recorded in medical notes as for all adverse events. However, they do NOT require completion of a SAE form and they do NOT require reporting to the WILL trial office.

The site PI/delegate should read the information entered and then complete Sections 9 and 10.

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 - Site details

2.1 Site name _____ | 2.2 Name of PI _____

2.3 Participant involved *Choose ONE only.* ***If mother and neonate are both involved, please report EACH on a separate SAE form.***

◯ Mother ◯ Fetus ◯ Neonate

Section 3 - Report type

3.1 Report type ◯ Initial Report ◯ Follow-up Report

SAE reference number: _ _ _ _ - N N

If **'Follow-up report'**, please proceed to **Section 7**.

Section 4 - Brief description of SAE

Please complete the the form in full and submit to BCTU within 24 hours. Where investigations or lab tests are appended, please ensure patient identifiers are replaced with study number only

4.1 Date of onset of event, even if not serious at that time: D D - M M M - Y Y Y Y

4.2 Date became serious: D D - M M M - Y Y Y Y

4.3 Date site became aware: D D - M M M - Y Y Y Y

4.4 Date first reported to BCTU *(may have been prior to form submission):* D D - M M M - Y Y Y Y

4.5 What was the outcome of the event?

◯ Resolved without sequelae ◯ Resolved with sequelae ◯ Resolving ◯ Not resolved ◯ Fatal ◯ Unknown

If **'resolved (with or without sequelae)'**, date resolved: *(and then proceed to **Section 5**)* D D - M M M - Y Y Y Y

If **'resolving', 'not resolved', or 'unknown'**, please ensure that follow-up information is submitted later on another SAE Form. Please now proceed to **Section 5**.

If **'fatal'**, please proceed to **Section 5**.

Section 5 - Expeditable SAEs

5.1 What was the nature of the expeditable SAE? *Please mark no or yes to EACH outcome. If there is more than one SAE to report, please use a separate SAE Form for each.*

Maternal death	◯ No	◯ Yes
Maternal stroke	◯ No	◯ Yes
Stillbirth	◯ No	◯ Yes
Neonatal death	◯ No	◯ Yes
Other	◯ No	◯ Yes

5.2 Please provide us with additional information to help us to understand the nature of the SAE.

If **death**, what was the date of death? D D - M M M - Y Y Y Y

If **death**, what was the cause of death?

If **death**, please proceed to **Section 7**. For all other SAEs, please proceed to **Section 6**.

Section 6 - Basis for SERIOUSNESS of event

6.1 Was this a life-threatening event? ◯ No ◯ Yes

If **yes**, nature of life-threatening event:

6.2 Was this a new hospitalisation? ◯ No ◯ Yes

NOTE: Some hospitalisations are not SAEs, because they are expected (given the high risk nature of the WILL participants) or they are unrelated to the intervention. See the WILL Protocol, Section 9.3.1 for examples.

If **yes**, Date of admission: D D - M M M - Y Y Y Y | Date of discharge: D D - M M M - Y Y Y Y

6.3 Was this a prolongation of an existing hospitalisation? ◯ No ◯ Yes

If **yes**, Date of admission: D D - M M M - Y Y Y Y | Date of discharge: D D - M M M - Y Y Y Y

6.4 Was this related to persistent or significant disability or incapacity? ◯ No ◯ Yes

6.5 Was this related to another condition that may jeopardise the pregnancy or may require intervention to prevent one of the other outcomes listed in Section 5? ◯ No ◯ Yes

If **yes**, please specify:

If **'initial report'** of this SAE, please proceed to **Section 8**.

Section 7 - Details of Follow-up Reports

If **'resolved', 'resolved with sequelae', or 'fatal'**, please ensure that question 4.5 is completed. If **'resolving', 'not resolved', or 'unknown'**, please ensure that follow-up information is submitted later on another SAE Form. Please now proceed to **Section 8**

7.1 Please provide us with additional information to help us to understand the nature of the SAE.

Please notify the site PI/delegate that the SAE form needs to be re-reviewed.

Section 8 - Details of person reporting (not site PI/delegate)

8.1 Name of person reporting: _____

8.2 Password of person reporting (as proxy for signature): *Must appear on Site Signature and Delegation Log*

_____

8.3 Date of password entry (auto-completed upon verification): D D - M M M - Y Y Y Y

Thank you. If not the site PI/delegate, the form is complete.

Section 9 - Causality assessment and PI/delegate sign-off (for PI/Delegate only)

9.1 Please confirm that the information in Sections 1-8 above is correct. ◯ No ◯ Yes

9.2 **Causality assessment:** *Please tick ONE of the following options, defined according to WILL Protocol, Section 9.4.2.*

- ◯ **Unrelated to intervention** *(ie, no evidence of any causal relationship)*
- ◯ **Unlikely to be related to intervention** *(ie, little evidence to suggest a causal relationship and is another reasonable explanation for the event)*
- ◯ **Possibly related to intervention** *(ie, some evidence to suggest a causal relationship, but other factors may have contributed to event)*
- ◯ **Probably related to the intervention** *(ie, evidence to suggest a causal relationship and influence of other factors is unlikely)*
- ◯ **Definitely related to the intervention** *(ie, clear evidence of a causal relationship and other possible contributing factors can be ruled out)*

9.2.1 If the event is **'Unrelated'** OR **'Unlikely to be related'**, please provide details of an alternative explanation for the event:

_____

_____

_____

_____

9.3 List any underlying co-morbidities, concomitant medications or investigations that may be relevant: *Where investigations or lab tests are appended, please ensure patient identifiers are replaced with study number only*

_____

_____

_____

_____

_____

_____

9.4 Name of PI or his/her medically-qualified delegate: *If not PI, delegate must appear on Site Signature and Delegation Log*

_____

9.5 Password of PI or his/her medically-qualified delegate (as proxy for signature): *If not PI, delegate must appear on Site Signature and Delegation Log*

_____

9.6 Date of PI or his/her medically-qualified delegate password entry (auto-completed upon verification): D D - M M M - Y Y Y Y

For additional support please call the WILL trial office during office hours on 0121 415 9109.

Thank you. The form is now complete.

For BCTU use only.

Section 10 - To be completed by Chief Investigator or named delegate (on Site Signature and Delegation Log)

10.1 Review of causality of the SAE to the intervention:

◯ Unrelated ◯ Unlikely to be related ◯ Possibly related ◯ Probably related ◯ Definitely related

If 'Possibly related', 'Probably related', or 'Definitely related', please proceed to question 10.2. Otherwise, proceed to next section.

10.2 Was the event expected, as per the WILL Protocol (Section 9.3.1)? ◯ Expected ◯ Unexpected

Section 11 - Signatures

11.1 Name of CI or delegate: *If not CI, delegate must appear on Site Signature and Delegation Log*

11.2 Password of CI or delegate (as proxy for signature): *If not CI, delegate must appear on Site Signature and Delegation Log*

11.3 Date of CI or delegate password entry (auto-completed upon verification): D D - M M M - Y Y Y Y

Section 12 - Office use only

12.1 Date received at BCTU: D D - M M M - Y Y Y Y

12.2 Name of person checking the form:

12.3 Signature of person checking the form:

12.4 Date reported to sponsor: D D - M M M - Y Y Y Y

12.5 Is the event related and unexpected? *Serious related and unexpected events require reporting to both the REC and sponsor*

◯ No ◯ Yes

12.6 Date Reported to REC: D D - M M M - Y Y Y Y