



12 - PROTOCOL DEVIATION FORM

Use this form to report any change, divergence or departure from the study design, procedures defined in the protocol, or GCP principles.

Please use one form for EACH event, even if multiple events occurred on the same date.

Section 1 - Woman's details

1.1 Woman's study number: <input style="width: 40px; height: 20px; border: 1px solid red;" type="text"/> <input style="width: 40px; height: 20px; border: 1px solid red;" type="text"/> <input style="width: 40px; height: 20px; border: 1px solid red;" type="text"/> <input style="width: 40px; 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 <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 - Event information

2.1 Date of event <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"/>
2.2 Date site became aware of protocol deviation: <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 3 - Details of protocol deviation

3.1 Please tell us the type of protocol deviation that occurred: *Please choose ONE option. (If more than one occurred, please report others on a separate '12 - PROTOCOL DEVIATION FORM(S)'.)*

- Inclusion/exclusion of participants
- Informed consent
- Randomisation
- Informing the participant's GP
- Non-adherence to the intervention (planned timing of delivery)
- Data collection, handling, and record-keeping
- Adverse event reporting
- Confidentiality and data protection
- Approvals (i.e, amendments, unapproved documentation)
- Other protocol deviations (please specify below)

If 'other', please specify:

3.2 Please provide us with a summary of the protocol deviation.

3.3 At your site, what remedial action(s) have you taken in response to this protocol deviation?

3.4 At your site, what action(s) have you taken to prevent this protocol deviation from happening again?

Section 4 - Details of individual completing form

Name: _____	Date of form completion <input type="text" value="D"/> <input type="text" value="D"/> <input type="text" value="M"/> <input type="text" value="M"/> <input type="text" value="M"/> <input type="text" value="Y"/> <input type="text" value="Y"/> <input type="text" value="Y"/> <input type="text" value="Y"/>
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Please submit form to the WILL trial office at BCTU. THE FORM IS NOW COMPLETE.

THE FOLLOWING SECTIONS ARE FOR BCTU OFFICE USE ONLY.

Section 5 - Assessment of up-escalation

5.1 Date received by BCTU

5.2 Is the deviation likely to affect to a significant degree: *Please mark no or yes for EACH option.*

The safety, physical or mental integrity of subjects in the trial

No Yes

The scientific value of the trial

No Yes

If yes, to either response option in Q5.2, please complete a *Serious Breach Assessment Form*

5.3 At the BCTU, what remedial action(s) have been taken in response to this protocol deviation?

5.4 At the BCTU, what action(s) have been taken to prevent this protocol deviation from happening again?

Section 6 - Details of individual reviewing form

Name: _____	Date <input type="text" value="D"/> <input type="text" value="D"/> <input type="text" value="M"/> <input type="text" value="M"/> <input type="text" value="M"/> <input type="text" value="Y"/> <input type="text" value="Y"/> <input type="text" value="Y"/> <input type="text" value="Y"/>
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Section 7 - Details of individual approving form

Name: _____	Date <input type="text" value="D"/> <input type="text" value="D"/> <input type="text" value="M"/> <input type="text" value="M"/> <input type="text" value="M"/> <input type="text" value="Y"/> <input type="text" value="Y"/> <input type="text" value="Y"/> <input type="text" value="Y"/>
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