

UNiTY Deviation Form

UNiTY is using direct data entry on REDCap. These paper CRFs are available to use if there is no immediate online access.

Please complete one CRF per participant deviation. Deviations involving multiple participants are recorded separately.

Couple Trial ID: /

Deviation number [assigned by system; Trial number plus instance number]

/ /

[Up to and including "Completed by" section editable only by Site PI AND Site Researcher role]

Section 1 - Event information

Has the deviation been discussed with the central trial team? *Tick one*

☐ Yes ☐ No

[If "Has the deviation been discussed with the central trial team?" answered **No**, show following instructional text]

If not, speak to the central team before completing the rest of the CRF.

[If "Has the deviation been discussed with the central trial team?" answered **Yes**, show Date of Deviation" AND "Date team became aware of the deviation" AND "Details of Deviation" section AND "Completed by" section AND Central Assessment of deviation - BCTU use" section AND "Review of deviation" section AND "Sign-off" section]

Date of deviation D D - M M M - Y Y Y Y

Date team became aware of the deviation D D - M M M - Y Y Y Y

Section 2 - Details of protocol deviation

Please describe the type of deviation that occurred. *Please only choose one option. If more than one has occurred, please report others on a separate form.*

- | | |
|--|---|
| <input type="radio"/> Inclusion/exclusion of participants | <input type="radio"/> Informed consent |
| <input type="radio"/> Randomisation | <input type="radio"/> Non-adherence to the intervention |
| <input type="radio"/> Data collection, handling and record-keeping | <input type="radio"/> Adverse event reporting |
| <input type="radio"/> Confidentiality and data protection | <input type="radio"/> Approvals (ie amendments, unapproved documentation) |
| <input type="radio"/> Other | |

[If "Please describe the type of deviation that occurred" answered **Other**, show "If other, please specify"]

If other, please specify

Please provide a summary of the deviation

Please explain any actions you have taken to correct this deviation and prevent similar deviations in the future.

Section 3 - Completed by

Must be completed by someone who has signed the Site Signature & Delegation Log

Name:

Date: D D - M M M - Y Y Y Y

Section 4 - Central assessment of deviation - BCTU use

["Central assessment of deviation - BCTU use" section and onwards editable only by users with BCTU TM Staff role]

Is the deviation likely to affect to a significant degree the safety, physical or mental integrity of subjects in the trial? *Tick one* ☐ Yes ☐ NoIs the deviation likely to affect to a significant degree the scientific value of the trial? *Tick one* ☐ Yes ☐ No[If "Is the deviation likely to affect to a significant degree the safety, physical or mental integrity of subjects in the trial?" answered **Yes** OR "Is the deviation likely to affect to a significant degree the scientific value of the trial?" answered **Yes**, show the following instructional text"]

If yes, complete a Serious Breach Assessment Form

Explain the actions at BCTU to correct this deviation and prevent similar deviations in the future.

Section 5 - Review of deviation

Name of person deviation reviewed by: _____

Section 6 - Sign off

Name

Date - -