

GHD Reversal Trial: Pregnancy Notification Worksheet

For female participants ONLY. This form is NOT REQUIRED in the event of a pregnancy being reported in the partner of a male participant.

Trial Number <input type="text"/>	Participant DOB <i>e.g. JAN-2017</i> <input type="text"/>
Site name <input type="text"/>	

Section 1 - Report Details

Date site became aware of pregnancy <i>e.g. 31-JAN-2017</i> D D - M M M - Y Y Y Y	Date of reporting to BCTU <i>e.g. 31-JAN-2017</i> D D - M M M - Y Y Y Y
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Section 2 - Consent details of pregnant trial participant

Has consent been given for pregnancy monitoring? <i>If consent has not been given do not complete the rest of this form</i> <input type="radio"/> Yes <input type="radio"/> No		
Date consent obtained <i>e.g. 31-JAN-2017</i> D D - M M M - Y Y Y Y	Consent form version number <input type="text"/>	PIS version number <input type="text"/>

Please complete the Pregnancy Notification section of this form within 14 days of the site becoming aware of pregnancy.

Section 3 - Pregnancy Notification

Start date of last menstrual period <i>e.g. 31-JAN-2017</i> D D - M M M - Y Y Y Y	Please tick if date unknown <input type="checkbox"/>
OR Gestation <input type="text"/> weeks	Please tick if unknown <input type="checkbox"/>
Date participant became aware of pregnancy <i>e.g. 31-JAN-2017</i> D D - M M M - Y Y Y Y	Please tick if date unknown <input type="checkbox"/>
Expected date of delivery <i>e.g. 31-JAN-2017</i> D D - M M M - Y Y Y Y	

Section 4 - Details of Form Completion: Pregnancy Notification

Name <i>Must appear on delegation log</i> <input type="text"/>	Job title <input type="text"/>
Signed <input type="text"/>	Date <i>e.g. 31-JAN-2017</i> D D - M M M - Y Y Y Y

Please enter the data onto the participant's electronic case report form: <https://www.trials.bham.ac.uk/GHD>

Please complete the Pregnancy Outcome section of this form once the information becomes available.

Section 5 - Pregnancy Outcome

Pregnancy outcome <i>Please tick one</i> <input type="radio"/> 1- No congenital abnormalities or birth defects <input type="radio"/> 2- Induced abortion, participant's choice <input type="radio"/> 3- Congenital abnormalities or birth defects <input type="radio"/> 4- Required admission to neonatal unit <input type="radio"/> 5- Therapeutic abortion, requested on medical reasons <input type="radio"/> 6- Miscarriage (loss of pregnancy before 24 weeks) <input type="radio"/> 7- Still birth (not born alive at or after 24 weeks) <input type="radio"/> 8- Neonatal death (death within 28 days of birth)
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If any of options 3 to 8 are selected, please also complete the GHD Reversal Trial Serious Adverse Event Reporting Form.

Gestational age at birth <i>weeks+days</i> <input type="text"/>	Date of birth of baby <i>e.g. 31-JAN-2017</i> D D - M M M - Y Y Y Y
Additional comments <input type="text"/> <input type="text"/> <input type="text"/>	

Note: the mother's relevant medical history and any medication taken during pregnancy should be documented in the medical notes.

Section 6 - Details of Form Completion: Pregnancy Outcome

Name <i>Must appear on delegation log</i>	Job title
PI (or delegate) signature:	Date <i>e.g. 31-JAN-2017</i> <u> </u> <u> </u> - <u> </u> <u> </u> <u> </u> - <u> </u> <u> </u> <u> </u> <u> </u>

Please enter the data onto the participant's electronic case report form: <https://www.trials.bham.ac.uk/GHD>

Thank you for completing the GHD Reversal Trial Pregnancy Notification Worksheet.