

Trial Exit/ Change Of Status Worksheet

If the participant has withdrawn from the trial, please complete the Trial Exit/ Change in Status Form.

Trial Number <input style="width: 40px; height: 20px;" type="text"/> <input style="width: 40px; height: 20px;" type="text"/> <input style="width: 40px; height: 20px;" type="text"/> <input style="width: 40px; height: 20px;" type="text"/>	Participant DOB e.g. JAN-2017 <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>
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Site name

Section 1 - Change of Status/ Notification of Withdrawal

Is the participant lost to follow up? *Please tick one* No Yes

If 'Yes', date lost to follow up *Please document date it was decided participant had been lost to follow up e.g. 31-Jan-2017*
 - -

If 'Yes', reason lost to follow up (if available)

Does the participant wish to withdraw from trial intervention, but is willing for further data to be collected according to protocol schedule? *Please tick one* No Yes

If 'Yes', date change of status (protocol follow up) e.g. 31-Jan-2017 - -

Does the participant wish to withdraw from trial intervention and protocol schedule, but is willing for routine data to be collected? *Please tick one* No Yes

If 'Yes', date change of status (routine follow up) e.g. 31-Jan-2017 - -

Does the participant wish to withdraw completely i.e. no further data will be collected? *Please tick one* No Yes

If 'Yes', date change of status (no further data) e.g. 31-Jan-2017 - -

If withdrawn completely from the trial, please provide main reason for withdrawal *Please tick one*

- Consent withdrawn: no reason given
- Consent withdrawn: participant/ parent unhappy with treatment allocation
- Consent withdrawn: participant/ parent no longer happy with trial follow up regimen
- Consent withdrawn: participant/ parent no longer interested in research
- Safety or compliance issues
- Other

If Other, please specify

Section 2 - Notification of Death

Has the participant died? *Please tick one* No Yes Date of death e.g. 31-JAN-2017 - -

Cause of death

Please complete the GHD Reversal Trial SAE form to record the patient's death.

Section 3 - Details of worksheet completion

Completed by (name) *This person must be listed on the delegation log*

PI (or delegate) signature:

Date form completed e.g. 31-JAN-2017 - -

Thank you for completing the GHD Reversal Trial Exit/ Change of Status Worksheet. Please enter all data onto the electronic case report form:

<https://www.trials.bham.ac.uk/GHD>