GHD Reversal Trial: Serious Adverse Event Reporting Form

To be completed for any serious adverse events occurring throughout the follow up period until the GH stimulation test is completed at Near Final Height.

Please send to BCTU within 24 hours with relevant reports.

Section 1 - Site Details

Site Name: _____

Name of PI: _____

Section 2 - Participant Details

Trial Number ☐☐☐☐

Participant DOB *e.g. JAN-2017* M M M Y Y Y Y

Section 3 - Report Type

(Use BCTU allocated unique SAE number if this is a follow-up or final report)

Report type *Please tick one*

◯ Initial Report ◯ Follow-up Report ◯ Final Report

If 'Follow-up' or 'Final' report, please insert unique SAE number

_____

Section 4 - Event Information

Signs and symptoms

_____

_____

_____

_____

_____

_____

Section 5 - Event Diagnosis

Diagnosis

_____

_____

_____

_____

Section 6 - Seriousness of Event

Death *Please tick one* ◯ Yes ◯ No

If yes, Date of death *e.g. 31-JAN-2017* D D - M M M - Y Y Y Y

Cause of death

_____

Life threatening event *Please tick one* ◯ Yes ◯ No

In-patient hospitalisation or prolongation of existing hospitalisation *Please tick one* ◯ Yes ◯ No

If yes, initial or prolonged? *Please tick one* ◯ Initial ◯ Prolonged

Date of discharge *e.g. 31-JAN-2017* D D - M M M - Y Y Y Y

Persistent or significant disability/incapacity *Please tick one* ◯ Yes ◯ No

Congenital anomaly or birth defect *Please tick one* ◯ Yes ◯ No

Other medical reason for reporting *Please tick one* ◯ Yes ◯ No

If yes, please specify _____

Section 7 - Details of Event

Date of onset *e.g. 31-JAN-2017* D D - M M M - Y Y Y Y

Date became serious: *e.g. 31-JAN-2017* D D - M M M - Y Y Y Y

Date site became aware *e.g. 31-JAN-2017* D D - M M M - Y Y Y Y

Event is ongoing? *Please tick one* ◯ Yes ◯ No

If 'No', date resolved *e.g. 31-JAN-2017* D D - M M M - Y Y Y Y

Section 8 - Details of Growth Hormone Therapy

To be completed for patients in the GH+ arm at the time of the event.

Name of GH preparation *Please see Table 1 at end of form* _____

Route of administration *Please tick one*
◯ Subcutaneous ◯ Oral ◯ IV ◯ Other

If 'Other', please specify _____

Dose ___ ___ µg/kg/day

Start date *For most recent GH therapy preparation and dose*
D D - M M M - Y Y Y Y

Date last dose received *e.g. 31-JAN-2017*
D D - M M M - Y Y Y Y

Action taken *Please tick one*
◯ None ◯ GH therapy stopped ◯ GH therapy delayed ◯ GH therapy reduced

If stopped, please provide date *e.g. 31-JAN-2017*
D D - M M M - Y Y Y Y

Did the event abate on stopping GH therapy? *Please tick one* ◯ Yes ◯ No ◯ Not applicable

If "yes", please provide details _____

Did the event reappear after introduction of GH therapy? *Please tick one* ◯ Yes ◯ No ◯ Not applicable

If "yes", please provide details _____

Section 9 - Causality Assessment

Causality must be assessment by a medically qualified doctor

Is the event related to the GH therapy? *Please tick one*
◯ 1-Unrelated ◯ 2-Unlikely to be related ◯ 3-Possibly related ◯ 4-Probably related ◯ 5-Definitely related

If the event is unrelated, please provide details of an alternative explanation for the event

_____

_____

Section 10 - Concomitant Medications

Has the patient taken any other drugs which may interact with the GH therapy or influence the SAE? *Please tick one*
◯ Yes (please details below) ◯ No

Please add any relevant concomitant medication to the following table.

Concomitant Medication					
Drug name	Route (oral, IV, SC, other-specify)	Dose/Unit/ Frequency (use Table 2 & 3)	Start date	End date	Tick if ongoing
			DD-MMM-YYYY	DD-MMM-YYYY	☐
			DD-MMM-YYYY	DD-MMM-YYYY	☐
			DD-MMM-YYYY	DD-MMM-YYYY	☐
			DD-MMM-YYYY	DD-MMM-YYYY	☐
			DD-MMM-YYYY	DD-MMM-YYYY	☐
			DD-MMM-YYYY	DD-MMM-YYYY	☐
			DD-MMM-YYYY	DD-MMM-YYYY	☐
			DD-MMM-YYYY	DD-MMM-YYYY	☐
			DD-MMM-YYYY	DD-MMM-YYYY	☐
			DD-MMM-YYYY	DD-MMM-YYYY	☐
			DD-MMM-YYYY	DD-MMM-YYYY	☐
			DD-MMM-YYYY	DD-MMM-YYYY	☐
			DD-MMM-YYYY	DD-MMM-YYYY	☐
			DD-MMM-YYYY	DD-MMM-YYYY	☐
			DD-MMM-YYYY	DD-MMM-YYYY	☐

Section 11 - Relevant Medical History (provide narrative if relevant to diagnosis)

List any underlying comorbidities or laboratory results and investigations that may be relevant *Where investigations or lab tests are appended, please ensure patient identifiers are replaced with trial number only*

Section 12 - Clinical Coding of SAE

Please provide the primary clinical coding for the event using CTCAE v5.0, which can be found at www.birmingham.ac.uk/GHD or in the GHD Reversal Trial site file

CTCAE term code ☐☐☐☐☐☐ | If other, please specify

CTCAE grade *Please tick one* ◯ Grade 1 ◯ Grade 2 ◯ Grade 3 ◯ Grade 4 ◯ Grade 5

Section 13 - Details of Person Reporting

Name of person reporting *Must appear on delegation log*

Job title of person reporting | Date reported to BCTU *e.g. 31-JAN-2017* D D - M M M - Y Y Y Y

Signature of person reporting | Date of signature *e.g. 31-JAN-2017* D D - M M M - Y Y Y Y

Signature of Principal Investigator | Date of PI signature *e.g. 31-JAN-2017* D D - M M M - Y Y Y Y

Please email completed Serious Adverse Event Reporting Form to BCTU within 24 hours with relevant reports to: GHDReversal@trials.bham.ac.uk

Section 14 - To Be Completed By Chief Investigator or Named Delegate

Where the CI is also the PI, this review should be delegated to a medically qualified doctor to ensure the causality is independently reviewed.

Name of intervention within event reviewed *Please see Table 1 at end of form* | Dose ___ ___ µg/kg/day

Confirmation of SAE status for event reported *Please tick one* ◯ SAE ◯ Not a SAE

If not an SAE, please document reason

Review of causality *Please tick one*

◯ 1-Unrelated ◯ 2-Unlikely to be related ◯ 3-Possibly related ◯ 4-Probably related ◯ 5-Definitely related

Expectedness should only be completed if causal relationship is classified as **3, 4 or 5 (possibly, probably or definitely related)** by the clinician at site or CI/ delegate. **The expectedness assessment must be made with reference to the reference safety information (RSI) as detailed within the live version of the protocol at the time of the event.**

Assessment of expectedness by Chief Investigator or delegate *Please tick one* ◯ Expected ◯ Unexpected

Section 15 - Signatures

In signing this form the Investigator or delegate confirms the **Causality** and **Expectedness** of the event

Name of CI or Delegate

Signature of CI or Delegate | Date of signature *e.g. 31-JAN-2017* D D - M M M - Y Y Y Y

Section 16 - Office Use Only

SAE reference number ☐☐☐☐☐☐☐☐

Event categorisation *Please tick one*

◯ Not an SAE ◯ SAE ◯ SAR ◯ SUSAR (fatal or life threatening) ◯ SUSAR (Non-fatal or life threatening)

Date reported to Competent Authority *e.g. 31-JAN-2017* D D - M M M - Y Y Y Y

Date reported to REC *e.g. 31-JAN-2017* D D - M M M - Y Y Y Y

Date Reported to Sponsor *e.g. 31-JAN-2017* D D - M M M - Y Y Y Y

Completed at BCTU by:

Name	Signature	Date of signature *e.g. 31-JAN-2017*
		D D - M M M - Y Y Y Y

Thank you for completing the GHD Reversal Trial Serious Adverse Event Reporting Form.

Table 1: GH Preparation List	
1.	Genotropin
2.	Humatrope
3.	Norditropin
4.	NutropinAQ
5.	Omnitrope
6.	Saizen
7.	Zomacton
8.	Other, please specify

Table 2: Frequency List	
1.	Daily
2.	Twice a day
3.	Three times a day
4.	Four times a day
5.	Alternate days
6.	Hourly
7.	4 hourly
8.	As desired
9.	If necessary
10.	Stat
11.	Slow release
12.	Other, please specify
13.	Unknown

Table 3: Dose Unit	
1.	mg
2.	µg
3.	g
4.	puffs
5.	units
6.	ml
7.	mg/ml
8.	mg/kg
9.	µg/ml
10.	Other, please specify
11.	Unknown