GHD Reversal Trial Healthcare Contacts Worksheet

To be completed from direct interview with the participant/ parent at the 6, 12, 24 and 36 month trial assessments. It is expected that participants will reach near final height by 36 months post randomisation. However, if this does not occur, please contact the Trial Team at BCTU for further guidance on additional follow up.

ALL sections to be completed for UK participants. Only SECTION 6 (Hospital Admissions) to be completed for Austrian participants.

Trial Number ☐☐☐☐ | Participant DOB *e.g. JAN-2017* M M M Y Y Y Y

Site name _____

Section 1 - Visit Details

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

Assessment point (months) *Please tick one*
◯ 6 ◯ 12 ◯ 24 ◯ 36 ◯ 48 ◯ 60

Additional visits after 36 months should only occur if near final height has not been reached. Please contact the GHD Reversal Trial team at BCTU for further information.

Section 2 - Primary Care Visits

Since the participant's last trial appointment, how many times have they been seen in primary care **due to their Growth Hormone Deficiency?**
Please put "0" if there have been no visits that were related to their GHD
__ __

Please provide details of EACH primary care visit **related to the participant's Growth Hormone Deficiency** in the section below. If additional primary care visits need to be reported, please complete another copy of the healthcare contacts worksheet.

1st Primary Care Visit

Where were they seen? *Please tick one*
◯ GP surgery ◯ GP walk in centre ◯ Out of hours clinic ◯ Home ◯ Other setting ◯ Unknown

If seen in an "Other setting", please specify _____

Who were they seen by?

GP *Please tick one* ◯ No ◯ Yes

Nurse *Please tick one* ◯ No ◯ Yes

Other healthcare professional *Please tick one* ◯ No ◯ Yes

If seen by an "Other healthcare professional", please specify _____

Unknown *Please tick one* ◯ No ◯ Yes

2nd Primary Care Visit

Where were they seen? *Please tick one*
◯ GP surgery ◯ GP walk in centre ◯ Out of hours clinic ◯ Home ◯ Other setting ◯ Unknown

If seen in an "Other setting", please specify _____

Who were they seen by?

GP *Please tick one* ◯ No ◯ Yes

Nurse *Please tick one* ◯ No ◯ Yes

Other healthcare professional *Please tick one* ◯ No ◯ Yes

If seen by an "Other healthcare professional", please specify _____

Unknown *Please tick one* ◯ No ◯ Yes

Section 3 - Outpatient Visits

Since the participant's last trial appointment, how many times have they been seen in outpatients **due to their Growth Hormone Deficiency?**
Please put "0" if there have been no visits that were related to their GHD
__ __

Please provide details of EACH outpatient visit **related to the participant's Growth Hormone Deficiency** in the section below. If additional outpatient visits need to be reported, please complete another copy of the healthcare contacts worksheet.

1st Outpatient Visit

Was the outpatient appointment a new referral or follow up visit? *Please tick one* ◯ New referral ◯ Follow up ◯ Unknown

Who were they seen by?

Consultant *Please tick one* ◯ No ◯ Yes

Junior doctor *Please tick one* ◯ No ◯ Yes

Nurse *Please tick one* ◯ No ◯ Yes

Other healthcare professional *Please tick one* ◯ No ◯ Yes

If seen by an "Other healthcare professional", please specify _____

Unknown *Please tick one* ◯ No ◯ Yes

2nd Outpatient Visit

Was the outpatient appointment a new referral or follow up visit? *Please tick one* ◯ New referral ◯ Follow up ◯ Unknown

Who were they seen by?

Consultant *Please tick one* ◯ No ◯ Yes

Junior doctor *Please tick one* ◯ No ◯ Yes

Nurse *Please tick one* ◯ No ◯ Yes

Other healthcare professional *Please tick one* ◯ No ◯ Yes

If seen by an "Other healthcare professional", please specify _____

Unknown *Please tick one* ◯ No ◯ Yes

Section 4 - A&E Visits

Since the participant's last trial appointment, how many times have they been seen in A&E? *Please put "0" if there have been no visits* __ __

Please complete the section below for EACH visit. If additional A&E visits need to be reported, please complete another copy of the healthcare contacts worksheet.

1st A&E Visit

Date of A&E visit *e.g. 31-JAN-2017* D D - M M M - Y Y Y Y

Following triage, who was the patient seen by?

Doctor *Please tick one* ◯ No ◯ Yes

Nurse *Please tick one* ◯ No ◯ Yes

Other healthcare professional *Please tick one* ◯ No ◯ Yes

If seen by an "Other healthcare professional", please specify _____

Unknown *Please tick one* ◯ No ◯ Yes

Was this episode related to the participant's Growth Hormone Deficiency? *Please tick one* ◯ Yes ◯ No

2nd A&E Visit

Date of A&E visit *e.g. 31-JAN-2017* D D - M M M - Y Y Y Y

Following triage, who was the patient seen by?

Doctor *Please tick one* ◯ No ◯ Yes

Nurse *Please tick one* ◯ No ◯ Yes

Other healthcare professional *Please tick one* ◯ No ◯ Yes

If seen by an "Other healthcare professional", please specify _____

Unknown *Please tick one* ◯ No ◯ Yes

Was this episode related to the participant's Growth Hormone Deficiency? *Please tick one* ◯ Yes ◯ No

Section 5 - Clinical Investigations

Has the participant undergone any clinical investigations (in addition to those documented on the Follow Up and/or Near Final Height forms as trial related investigations) since their last trial appointment **due to their growth hormone deficiency**? *Please tick one* ◯ Yes ◯ No

Please complete the table below for all growth hormone related investigations conducted.

Clinical Investigations	
	Number performed (please put "0" if none)
Additional Serum IGF-1	__ __
Serum IGF-BP3	__ __
Additional GH Stimulation Test	__ __
Additional Lipid Profile Test	__ __
Thyroid Function Test	__ __
Coeliac Antibodies Test	__ __
Blood Cortisol	__ __
Additional X-ray	__ __
MRI Scan	__ __
Other 1 please specify_____	__ __
Other 2 please specify_____	__ __
Other 3 please specify_____	__ __

Section 6 - Hospital Admissions

Please complete this section for both **UK and Austrian** participants

Since the participant's last trial appointment, how many times have they been admitted to hospital? *Please put "0" if there have been no admissions*

__ __

Please complete the section below for EACH visit. If additional hospital admissions need to be reported, please complete another copy of the healthcare contacts worksheet.

1st Hospital Admission

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

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

Participant admitted from *Please tick one* ◯ Home ◯ A&E ◯ GP surgery ◯ Outpatients ◯ Other ◯ Unknown

If Other, please specify _____

Was the participant triaged in A&E prior to the hospital admission? *Please tick one* ◯ No ◯ Yes ◯ Unknown

Type of admission *Please tick one* ◯ Elective ◯ Emergency

Location of participant during admission (please put "0" if did not stay on relevant ward type)

	Days on ward	Start date	Stop date
General ward (Level 0)	__ __	D D - M M M - Y Y Y Y	D D - M M M - Y Y Y Y
Acute (Level 1)	__ __	D D - M M M - Y Y Y Y	D D - M M M - Y Y Y Y
HDU (Level 2)	__ __	D D - M M M - Y Y Y Y	D D - M M M - Y Y Y Y
PICU/ ICU (Level 3)	__ __	D D - M M M - Y Y Y Y	D D - M M M - Y Y Y Y

Number of theatre visits during hospital admission (put "0" if did not go to theatre)
__ __

Please outline procedures undertaken if visited theatre
_____

Was the episode related to the participant's Growth Hormone Deficiency? *Please tick one* ◯ Yes ◯ No

Clinical coding of 1st hospital admission

Please provide the primary reason for the hospital admission using CTCAE v5.0 clinical coding, 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

Please review details of the hospital admission against the criteria for a Serious Adverse Event (SAE) defined in Section 9 of the GHD Reversal Trial Protocol. If the definition of an SAE is met, please complete an SAE Reporting Form as soon as possible and send a copy to the Trials Team: GHDReversal@trials.bham.ac.uk

2nd Hospital Admission

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

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

Participant admitted from *Please tick one* ◯ Home ◯ A&E ◯ GP surgery ◯ Outpatients ◯ Other ◯ Unknown

If Other, please specify _____

Was the participant triaged in A&E prior to the hospital admission? *Please tick one* ◯ No ◯ Yes ◯ Unknown

Type of admission *Please tick one* ◯ Elective ◯ Emergency

Location of participant during admission (please put "0" if did not stay on relevant ward type)

	Days on ward	Start date	Stop date
General ward (Level 0)	__ __	D D - M M M - Y Y Y Y	D D - M M M - Y Y Y Y
Acute (Level 1)	__ __	D D - M M M - Y Y Y Y	D D - M M M - Y Y Y Y
HDU (Level 2)	__ __	D D - M M M - Y Y Y Y	D D - M M M - Y Y Y Y
PICU/ ICU (Level 3)	__ __	D D - M M M - Y Y Y Y	D D - M M M - Y Y Y Y

Number of theatre visits during hospital admission (put "0" if did not go to theatre) __ __	Please outline procedures undertaken if visited theatre _____

Was this episode related to the participant's Growth Hormone Deficiency? *Please tick one* ◯ Yes ◯ No

Clinical coding of 2nd hospital admission

Please provide the primary reason for the hospital admission using CTCAE v5.0 clinical coding, 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

Please review details of the hospital admission against the criteria for a Serious Adverse Event (SAE) defined in Section 9 of the GHD Reversal Trial Protocol. If the definition of an SAE is met for participants in control arm (continuing GH therapy), or participants that have re-commenced GH therapy in the experimental arm (GH withdrawal), please complete the GHD Reversal Trial SAE form as soon as possible and send a copy to the Trials Team: GHDReversal@trials.bham.ac.uk

Section 7 - 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* D D - M M M - Y Y Y Y

Thank you for completing the GHD Reversal Trial Healthcare Contacts Worksheet. Please enter all data onto the participant's electronic case report form:

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

Note: If a participant has NOT reached Near Final Height with epiphyseal fusion by the time of the 36 month assessment, please contact the GHD Reversal Trial team at BCTU for further guidance on the additional follow up required.