GHD Reversal Trial: Baseline Data Collection Worksheet

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

Section 2 - Ethnicity

Participant's self declared ethnicity *Please tick one*

- ◯ British European
- ◯ Irish European
- ◯ Central European
- ◯ East European
- ◯ North European
- ◯ South European
- ◯ West European
- ◯ North African
- ◯ Sub-Saharan African
- ◯ Middle Eastern
- ◯ Indian
- ◯ Pakistani
- ◯ Bangladeshi
- ◯ Chinese
- ◯ Other East Asian
- ◯ South East Asian
- ◯ Caribbean
- ◯ European and East Asian
- ◯ European and South Asian
- ◯ European and Sub-Saharan African
- ◯ European and Caribbean
- ◯ Any Other Mixed Background*
- ◯ Other*
- ◯ Declined to give information

*If 'Any other mixed background' or 'Other', please specify _____

Section 3 - Clinical Details

Participant's height (mean) *See Protocol V4.0, Section 10.5 for clarification of measurement procedure.* ___ ___ ___ . ___ cm

Participant's weight ___ ___ ___ . ___ kg

Target height *Calculated as: (Mother's height + Father's height) / 2 ± 6.5cm. The 6.5cm should be added for males and subtracted for females.*
___ ___ ___ . ___ cm

Tanner stage (P) *Please tick one* ◯ Stage 2 ◯ Stage 3 ◯ Stage 4 ◯ Stage 5

Section 4 - Details of Diagnosis

GH Stimulation Tests at Diagnosis

	Date sample taken	Peak GH	Test used	Was the test sex steroid primed?
1st stimulation test	D D - M M M - Y Y Y Y	___ ___ . ___ µg/L	◯ Insulin tolerance test ◯ Arginine ◯ Glucagon ◯ Other	◯ Yes ◯ No
2nd stimulation test	D D - M M M - Y Y Y Y	___ ___ . ___ µg/L	◯ Insulin tolerance test ◯ Arginine ◯ Glucagon ◯ Other	◯ Yes ◯ No

If 'Other' test used for 1st stimulation test, please specify _____

If 'Other' test used for 2nd GH stimulation test, please specify _____

Diagnostic peak GH cut off used at diagnosis ___ ___ . ___ µg/L

Serum IGF-1 at diagnosis

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

Serum IGF-1 assay used *Please tick one*

- ◯ IDS iSYS
- ◯ Immulite 2000 Family
- ◯ Roche Elecsys
- ◯ Siemens Immulite
- ◯ Diasorin Liaison ® XL
- ◯ Other

If Other, please specify _____

Serum IGF-1 concentration ___ ___ ___ . ___ | Serum IGF-1 unit *Please tick one* ◯ nmol/L ◯ µg/L ◯ ng/ml ◯ Other

If other Serum IGF-1 unit, please specify _____

Date of I-GHD diagnosis

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

Section 5 - Routine Re-test Results

GH stimulation re-test

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

Peak GH ___ ___ . ___ µg/L

Test used *Please tick one* ◯ Insulin tolerance test ◯ Arginine ◯ Glucagon ◯ Other

If 'Other' test has been used, please specify

Was the test sex steroid primed? *Please tick one* ◯ Yes ◯ No

Please note: for the purposes of the GHD Reversal Trial, insulin tolerance test, glucagon and arginine are stipulated as the required GH stimulation tests within the protocol.

Serum IGF-1 at re-test

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

Serum IGF-1 assay used *Please tick one*

- ◯ IDS iSYS
- ◯ Roche Elecsys
- ◯ Diasorin Liaison ® XL
- ◯ Immulite 2000 Family
- ◯ Siemens Immulite
- ◯ Other

If Other, please specify

Serum IGF-1 concentration ___ ___ ___ . ___

Serum IGF-1 unit *Please tick one* ◯ nmol/L ◯ µg/L ◯ ng/ml ◯ Other

If other Serum IGF-1 unit, please specify _____

Section 6 - Growth Hormone Therapy

Date GH therapy first commenced *e.g. JAN-2017* M M M Y Y Y Y

Details of GH therapy prior to re-test

Please provide details of the participant's last GH therapy preparation and dose immediately prior to re-test in the table below.

GH Therapy Immediately Prior to Re-test			
GH preparation (use Table 1)	Dose	Start date	Date of last dose prior to re-test
_____	___ ___ µg/kg/day	D D - M M M - Y Y Y Y	D D - M M M - Y Y Y Y

Has the participant been prescribed GH therapy since randomisation? *Please tick one* ◯ Yes ◯ No

Please record any GH therapy prescribed from randomisation onwards on the GHD Reversal Trial Medication Form

Section 7 - Concomitant Medication

Is the participant taking any other endocrine medication (including both new prescriptions since randomisation, and ongoing medicines at the time of randomisation)? *Please tick one* ◯ Yes ◯ No

Please record details of endocrine medication on the GHD Reversal Trial Medication Form

Section 8 - Bone-related Data

It is recommended that the X-ray is performed on the participant's non-dominant hand where possible, and the same hand should be X-rayed throughout the trial. Bone Xpert X-ray analysis is conducted at Great Ormond Street Hospital (UK participants) and Kepler Universitätsklinikum (Austrian participants). Results are sent to the participant's site and should be entered onto the trial database by site staff. Please see section 10.4 of the protocol for further details of the hand X-ray process.

Has a hand X-ray been performed? *Please tick one* ◯ Yes ◯ No

Specify hand used for X-ray *Please tick one* ◯ Dominant ◯ Non-dominant

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

Bone age __ __ . __ __ years

Bone Health Index __ . __ __

Section 9 - Biochemistry

Lipid Profile

	Date sample taken	Not done	Reading	Unit	Within normal reference range?
Fasting serum triglyceride	D D - M M M - Y Y Y Y	☐	__ __ __ . __ __	◯ mmol/L ◯ mg/dL	◯ Yes ◯ No
Fasting total serum cholesterol	D D - M M M - Y Y Y Y	☐	__ __ __ . __ __	◯ mmol/L ◯ mg/dL	◯ Yes ◯ No

Section 10 - Withdrawal

Is the participant/ parent willing to continue in the trial? *Please tick one* ◯ Yes ◯ No

If the participant is NOT willing to continue in the trial, please complete the Trial Exit/ Change of Status Form.

Section 11 - 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 Baseline Data Collection Worksheet. Please enter all data onto the participant's electronic case report form:

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

In addition to the baseline data collection form, please ensure the following are also completed at the time of baseline assessment:

-Child Health Utility-9D questionnaire (to be completed by the participant)

-GHD Reversal Trial Medication Form

Table 1: GH Preparation List

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