



GHD Reversal Trial: Signature and Delegation Log

Site Name:	
-------------------	--

Principal Investigator:	
--------------------------------	--

Completion of the Delegation of Duties Log

The Principal Investigator (PI) should complete the first table. All other staff who will work on the GHD Reversal Trial at site should be added to the second table. If a member of staff joins or leaves the trial, please update the original delegation log and email a copy (all pages) to BCTU:

GHDReversal@trials.bham.ac.uk

Legend

Use this legend to complete the Tasks Delegated column in the tables below. For each individual listed in the Name column, enter the letter(s) (e.g. a c, e) from the legend below that correspond to their protocol-related duties. If there are significant protocol related duties that are not already included in the legend, please add them in the empty space provided in the legend table below.

A	Screening and selection of potential trial participants	I	Medical care of participant	Q	Source data and CRF review, and sign off (PI ONLY)
B	Provision of trial information to potential participants	J	Sample collection for trial purposes	R	Performing hand X-rays
C	Affirmation of inclusion and exclusion criteria (CLINICIAN ONLY)	K	GH therapy compliance assessment	S	Transfer of X-ray images to GOSH
D	Obtain informed consent (CLINICIAN ONLY)	L	Adverse event assessment and reporting (including SAE reporting)	T	Investigator Site File maintenance
E	Participant randomisation	M	SAE causality assessment (CLINICIAN ONLY)	U	Other (please list):
F	Prescribing GH therapy	N	Completion of CRFs and DCFs	V	Other (please list):
G	Distribution of trial supplies	O	Correction of CRFs	W	Other (please list):
H	Physical examination of participant	P	Data entry	X	Other (please list):

The PI should sign below at Site Close-Out

I have reviewed the information on this log and have found it to be accurate. All delegated duties were performed with my authorisation.

PI Signature: _____ **PI Initials:** _____ **Site close out date:** __ / __ / ____



GHD Reversal Trial: Signature and Delegation Log

Principal Investigator (PI) Duties

This table should list the PI only, and should be used to document any changes in PI at site.

Name of Principal Investigator (Please print)	Signature of PI	Date of Signature of PI (dd/mmm/yyyy)	Initials of PI	PI Tasks (see legend)	Date of Duties	
					From (dd/mmm/yyyy)	To (dd/mmm/yyyy)



GHD Reversal Trial: Signature and Delegation Log

Trial Staff Duties

**** PI Signature**

By initialling an entry, I confirm that the person completing the entry is authorised to perform the study procedures in the tasks section, and that the person is qualified to undertake these tasks. I also confirm that the person is appropriately informed about the study protocol and relevant study procedures

Name (please print)	Trial Role	Tasks Delegated by PI* (see legend above)	Initials	Signature	Date of signature	Date of Duties		PI initials**	Date of PI Signature
						From (dd-mmm-yyyy)	To (dd-mmm-yyyy)		



GHD Reversal Trial: Signature and Delegation Log

Name (please print)	Trial Role	Tasks Delegated by PI* (see legend above)	Initials	Signature	Date of signature	Date of Duties		PI initials**	Date of PI Signature
						From (dd-mmm-yyyy)	To (dd-mmm-yyyy)		