JOINT RESEARCH AND DEVELOPMENT OFFICE

Somers Clinical Research Facility

Setting up a Delegation of Responsibilities and Signature Log for trial related duties

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Author: Praseeda Thaikalloor	Sign: P and.	Designation: Clinical Trials Manager
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Revision History			
Previous version	Comments	Reviewed by	Date archived
GOSH ICH/06/S18 V4.0, 15/01/2014	Review and changes to add CI/PI signature to the delegation log prior to the activity	Emma Pendleton	9th August 2016

	being undertaken by delegates		
GOSH ICH/06/S18 V 3.0, 26/01/2012	Review and minor changes	Dr Lorna Gibson	15/01/2014
GOSH ICH/06/S18 V2.0	Time for review	Dr Sabine Kläger	26/01/2012
GOSH ICH/06/S18 V1.0	First Issue	Emma Pendleton	02/03/2009

1. Scope /Background

This SOP is applicable to all the clinical trials sponsored, co-sponsored by the Great Ormond Street Hospital for Children NHS Foundation Trust. The SOP is applicable to Chief Investigators (CI), PIs, and delegated trial team members involved in Trust-sponsored CTIMPs and the Joint R&D Office Clinical Trials Team with responsibility for performing sponsor activities on behalf of the Trust.

2. Legal basis

The legal basis for this OP is Council Directive 2001/20/EC[1] (Article 15). This Directive (published in 2001) is also known as the Clinical Trials Directive (CTD) and relates to the implementation of Good Clinical Practice in the conduct of clinical trials on medicinal products for human use. In the UK the CTD was transposed into law by the 'The Medicines for Human use (Clinical Trials) Regulations 2004: SI 2004 No 1031[2]. The UK Regulations took effect on 1 May 2004 and then further amendments.

Under ICH GCP the Investigator should have available an adequate number of qualified staff and adequate facilities for the foreseen duration of the trial to conduct the trial properly and safely[1]. This includes the documentation of all those personnel involved in the trial.

3. Purpose

This SOP is intended to inform the investigator to set up a combined delegation and signature sheet to document the name of the personnel responsible for significant trial-related duties, including signatures of all persons who enter or correct data on CRFs. By

doing so, the Investigator will ensure full accountability of all those people responsible in the conduct of the trial, irrespective of length of their involvement.

4. Definitions

One of the principles of ICH Good Clinical Practice (GCP) is that each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task(s). Under ICH GCP the Investigator can delegate significant trial-related duties. In doing so the Investigator should maintain a list of appropriately qualified persons to whom he/she has delegated the duties to, no matter how short or long their duration is[1].

5. Personnel responsible

The responsibility for setting up the Delegation of Responsibilities and Signature Log lies with the Principal Investigator. The information recorded on this document will be used during monitoring.

6. Procedure

The Principal Investigator of the trial will need to list all the personnel involved in significant duties of the trial. The form to be used is identified as Form 25 appendix 1.

Examples of trial significant duties include:

- Subject screening
- Consent discussions
- Consenting
- Inclusion/exclusion assessment
- Dispensing
- Trial visits
- Venepuncture
- Trial procedures
- Adverse Event Recording
- Pharmacovigilance (S/AE/R Reporting)
- Source data completion
- Case Report Form (CRF) completion
- Medical care of trial subject
- IMP management
- Data management

- Laboratory sample processing
- Sample shipments (if applicable)
- Archiving of study documents
- Maintaining Investigator site files
- Other Tasks e.g. Amendment Submissions

It is important to realise that this needs to be done for all personnel however limited their involvement in the trial or the duration of their involvement; as every activity on a clinical trial needs to be accountable. It is also the responsibility of the Investigator to ensure that all the personnel are trained to perform their delegated duty(ies) according to the protocol and regulations. The Investigator is also obliged to ensure that all staffs are GCP trained and they renew their GCP training every two years according to the SOP GOSH/ICH/16/CT07 for Training for Clinical Research

The Investigator needs to ensure that the personnel listed on the Delegation Log also sign and initials the document. The log should be signed and dated by the delegate and the PI prior to the activity being undertaken by the individual. The signature serves a number of functions:

1. The person is confirming that he/she is confident of performing that delegated task. Only authorised personnel who have signed the delegation sheet are allowed to enter or correct data in the CRF.
2. The signature of the person on the CRF will be cross-checked with the signature on the Delegation Log by the monitor during monitoring.

The Delegation of Responsibilities and Signature Log is an essential document and will need to be maintained in the Trial Master File (TMF) or Site File depending on the arrangements as per each trial. The protocol specific training provided to the delegates should be recorded in the training log.

7. Associated documents and SOPs*

Document Name	File Path	Author
Appendix 1 : Delegation of Responsibilities and Signature Log	**Available upon request**	**Avani Shukla**

8. Recommendations

NA

9. References

Commission Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products. Official Journal of the European Communities, 9 April 2005; L91/13-19

DIRECTIVE 2001/20/EC of the European Parliament and of The Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use. Official Journal of the European Communities, 1 May 2001; L121/34-44

ICH Harmonised Tripartite Guideline for GCP: adopted in Europe by CPMP in 1996 and published as CPMP/ICH/135/95/Step 5 in Eudralex: The Rules Governing Medicinal Products in the European Union: Volume 3-Guidelines (3CC1A).

Statutory Instrument 2004 No. 1031. The Medicines for Human Use (Clinical Trials) Regulations 2004 The Stationary Office Limited. ISBN 0110490487

Statutory Instrument 2006 No. 1928. The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 The Stationary Office Limited. ISBN 0110748611

10. Appendices

*all these documents are available electronically