JOINT RESEARCH AND DEVELOPMENT OFFICE

Somers Clinical Research Facility

Subject Screening, Enrolment and Identification Logs

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Previous version	Comments	Reviewed by	Date archived
GOSH ICH/06/S20/Version 4.0 (15/01/2014)	Minor corrections from Version 3	Emma Pendleton	09/08/2016
GOSH ICH/06/S20/Version 3.0 (18/02/2012)	Document review.	Dr Lorna Gibson	15/01/2014
GOSH ICH/06/S20/Version 2.0 (02/03/2009)	Document review.	Dr Sabine Kläger	18/02/2012
GOSH	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.

2. Legal basis

The legal basis for this OP is Council Directive 2001/20/EC (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. The UK Regulations took effect on 1 May 2004 and then further amendments.

3. Purpose

This SOP is intended to inform the investigator about which templates to use to document the subjects who are screened for pre-trial entry, to code the subjects who meet the inclusion criteria and to keep a chronological list of subject enrolment. The PI will be able to use the information recorded on the logs to relay to the Joint R&D Office on request for recruitment numbers.

4. Definitions

A **subject screening log** is an essential document recording subjects who were reviewed for possible entry into a clinical trial they were "screened" for entry. This document should be filed in the Trial Master file (TMF).

A **subject enrolment log** is an essential document recording the chronological enrolment of subjects by trial number (code given for trial subject). This document should be filed in the TMF.

A **subject identification code list** is a confidential list of names and some personal details of all subjects enrolled and allocated trial numbers (code for each subject). This list is also

used to allow an investigator to reveal identity of a subject. This should be the only document in the Trial Site File that has any patient identifiable data on, excluding informed consent forms.

Please note that the above does not apply to blinded, randomised trials. The delegated Clinical Trials Manager in the Joint R&D Office should be contacted for guidance on randomised, blinded trials.

Under ICH GCP the Principle Investigator (PI) should be able to demonstrate a potential for recruiting the required number of suitable subjects within the agreed recruitment period specified by the protocol (ICH GCP 4.2.1). This is achieved through the subject screening, enrolment and identification code logs. The logs also serve the purpose to collect information on withdrawals and number of subjects who concluded the trial.

The dates recorded on the subject enrolment log must predate all trial-related interventions and should correspond with the date on the signed informed consent form.

5. Personnel responsible

Overall responsibility for setting up and maintaining accuracy of subject screening, enrolment and identification log and ensuring corrections made to these logs are done so in accordance with GCP and the responsibility lies with the PI. The PI will need to ensure that such documents are securely stored as they contain patient identifiable data.

6. Procedure

The PI of the trial will need to keep a separate list of all the subjects screened for potential entry in the trial. This list may be used to assign a code to subjects who have met the inclusion criteria. Thereafter, to ensure confidentiality, the PI will need to use this code instead of the subject's name on documents such as the Case Report Form, lab results and other documents to maintain patient confidentiality. The screening and enrolment log can be combined if more feasible in some trials and can also be kept electronically in a secured manner. If kept electronically, they should be accessible during monitoring, audits or inspections. These should be printed and filed in the TMF/ISF upon trial completion before archiving. A printed copy can also be filed prior to monitoring, audits or inspection for ease of access.

The PI needs to document the chronological entry of the subjects in the trial. This log is useful for recruitment tracking as well as withdrawals and trial completion.

The PI needs to document some patient identifiable information relating to a subject in the trial (for example: Name, Hospital Number, Date of Birth) so that a patient's trial number can easily be linked back to their trial medication (in a blinded, randomised trial) in an emergency. This information could be required in the event of emergency unblinding related to a Serious Adverse Event/Reaction or SUSAR and should be kept in the Trial Master File or clearly referenced area.

The following templates can be used and are available upon request from the designated Clinical Trials Manager in the Joint R&D Office:

7. Associated documents and SOPs*

Document Name	File Path	Author
Subject Screening/Enrolment Log:F26	Available upon request from the Joint R&D Office	Avani Shukla
Subject Enrolment Log:F27	Available upon request from the Joint R&D Office	Avani Shukla
Subject Identification Code List: F47	Available upon request from the Joint R&D Office	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