JOINT RESEARCH AND DEVELOPMENT OFFICE

Somers Clinical Research Facility

Training Requirements for staff participating in Clinical Research

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Revision History			
Previous version	Comments	Reviewed by	Date archived

1. Scope /Background

This SOP is applicable to all the CTIMPs and other interventional trials sponsored, co-sponsored by 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.

3. Purpose

The purpose of this SOP is to describe the procedures that investigators should put in place to demonstrate that each individual involved in conducting a trial shall be qualified by education, training and experience to perform their task.

4. Definitions

Curriculum Vitae: A document to demonstrate that you are qualified by education, training and experience to conduct the research.

5. Personnel responsible

It is the responsibility of the Chief Investigator to ensure that study team have received all the necessary training to enable them to take the delegated duties in the delegation log.

6. Procedure

6.1 GCP Training

Joint R&D Office conduct Good Clinical Practice course supported by National Institute of Health Research. GCP course dates will be circulated to the trust staff via R&I Newsletter and GOSH Newsletter by the Joint R&D Office. Investigators are advised to register for the course using the NIHR Learning Management System. GCP courses can be 'face to face' or 'on-line' courses. Certificates from externally approved providers are also acceptable.

Additional workshops those are relevant for GCP training, e.g. a workshop for informed consent and GCP training for Pharmacy staff are also available from NIHR via LMS.

It is recommended that GCP refresher courses are carried out every 2 years by relevant staff involved in CTIMPs. Continued failure to attend a refresher course can be seen as non-compliance to GCP and should be bought to the attention of the delegated member of staff working in the Joint R&D Office who will decide the appropriate action to take.

6.2 Study Specific Training

CI/PI is responsible to ensure the site staff are appropriately qualified and trained to do the study specific activities and it is documented in the site file.
All the staff should receive training on protocol and study specific activities before they sign the delegation log and enable to undertake the activities. This training should be maintained throughout the study. The training provided should be documented using the training records attached to this SOP.

6.3 SOP training

Chief Investigator is responsible to ensure the site staffs are appropriately trained in the sponsor's SOPs related to the trial conduct. When a new SOP will be announced by a member of the Joint R&D Office, emails will be sent out to relevant Investigators and staff as and when needed. Investigators should acknowledge that they read and understood the content of the SOP using the SOP training record.

6.4 Training Records

Training documentation for all the trial staff should be stored securely and easily accessible for audit/monitoring and inspection purposes. The documentation should contain

1. A signed and dated CV

2. GCP or other relevant certificate as appropriate
3. Evidence of study specific training
4. Evidence of SOP training
5. Evidence of any relevant external Trust Training
6. A current Job description

If any of the above documentation is stored separately, a file note should be kept in the site file to state the location.

6.5 Joint R&D Office

Joint R&D office staff keeps the updated CV and GCP certificates for the investigators as part of the governance checks.

7. Associated documents and SOPs*

Document Name	File Path	Author
Study Specific Training Record: Group	Available upon Request	Praseeda Thaikalloor
Study Specific Training Record: Individual	Available upon Request	Praseeda Thaikalloor
CV template:	http://www.hra.nhs.uk/resources/applying-for-reviews/applying-for-approvals-template-documents/	

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 product

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

Health Research Authority website, Available from

http://www.hra.nhs.uk/resources/before-you-apply/roles-and-responsibilties/sponsor/

(Accessed on 27/06/2016)

ICH Harmonised Tripartite Guideline for Good Clinical Practice, Step 4, May 1996.

The Medicines for Human Use (Clinical Trials) Regulations 2004, Available from **The Medicines for Human Use (Clinical Trials) Regulations 2004**

(Accessed on 27/06/2016)

10. Appendices

*all these documents are available electronically