STANDARD OPERATING PROCEDURE: Performing and Documenting Training for Research Staff

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SOP SUMMARY

This document covers the procedure for performing and documenting training for staff involved with clinical research.

The Trust monitors the implementation of and compliance with this policy in the following ways:

Monitoring of implementation and compliance with this procedure will be undertaken by the Executive Medical Director, Research manager, Research lead, R&D department staff and R&D group.

Services	Applicable	Comments
Trustwide	✓	
Essex MH&LD		
CHS		

ESSEX PARTNERSHIP UNIVERSITY NHS FOUNDATION TRUST

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1. BACKGROUND

This SOP outlines the processes in place to ensure that Clinical Research Teams are appropriately trained, have the medical, scientific and clinical knowledge to conduct trials competently and their training and qualifications are documented.

The Sponsor shall ensure appropriate management and documentation of research (clinical trials) to meet ethical and regulatory requirements. Prior to trial initiation, the Sponsor should ensure that the study has been approved by the Research & Development Office.

- Each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective tasks. (ICH GCP 2.8)
- Employers of staff undertaking health and social care research have responsibility for developing and promoting a high quality research culture in their organisations and for ensuring that their staff are supported in, and held to account for, the professional conduct of research, including research integrity. Employers of research staff should ensure appropriate individual learning and competence (UK Policy Framework for Health and Social Care Research, 2017, 9.20)

2. PURPOSE

To ensure all staff participating in clinical research are appropriately qualified and trained to meet research governance, regulatory and Trust requirements.

To ensure new research staff are appropriately trained and are able to produce evidence of such training.

All staff involved with Clinical Trials, and all research department staff, regardless of workload, shall attend Good Clinical Practice training.

Applicable to Clinical research team – All staff working in Trust-based clinical research including Clinical Leads for Research; Principal Investigators; Co-investigators; Research Network Manager; Network Research Lead Nurse; Research Nurses; Clinical Studies Officers, Research Delivery Co-ordinators, Data Managers; Trial Co-ordinators; R&D staff; Research Radiographers and Radiologists; Clinical Trials Assistants; Clinical Trials Pharmacists; Pharmacy technicians; Statisticians.

3. RESPONSIBILITIES

3.1 Training

The Trust is responsible for providing appropriate training and development for all research staff. Staff must ensure they have competed all the mandatory training required by the employer(s).

The Sponsor is responsible for ensuring staff participating in clinical research are appropriately qualified and trained. If the Trust is the Sponsor, this duty has been delegated to the CI/PI.

The CI/PI is responsible for appropriate training of research staff and for ensuring all staff participating in clinical trials shall attend GCP training as soon as possible.

CI/PI must also ensure that research staff without GCP training shall not be involved in obtaining consent for research activities.

The training of R&D staff is the responsibility of the R&D Manager. The R&D manager is responsible for ensuring that training records are maintained and are available for audit. All staff must attend accredited GCP training which must be updated every 2 years. It is realised that Chief Investigators; Principal Investigators; Co investigators; Clinical Leads for Research Networks, Radiologists and staff working in other specialities are involved in research and need access to appropriate clinical research training. However whilst appropriate training will be provided, these professional groups will be responsible for their own management of training needs and maintenance of training records and associated documentation.

It must be recognised that each team member will have different training needs according to their qualifications and experiences. An assessment of individual need should be performed on appointment to establish a baseline framework of skills and competencies. This will serve to identify specialist knowledge that can be shared, and gaps in knowledge to be filled. Following the initial assessment, training needs will be formally reviewed at the time of the Trust appraisal i.e. at 6 months and 12 months from appointment and then annually. Individual training needs may be addressed by a combination of internal/external training courses and national symposia/conferences. Managers should also consider a variety of other activities including e-learning programmes, video/sound tapes, secondments/visits to other areas and departments.

3.2 Induction

All new staff are required to complete mandatory training "*within the first 12 weeks of employment, extenuating circumstances can be taken into consideration.*" (HR21, 2.4)

All newly appointed members of the Clinical Research Teams will be given an individual induction timetable which will include a training needs assessment; an introduction to Research SOP's; an introduction to R&D manager; time spent shadowing an appropriate senior member of the research team.

3.3 Training records

The R&D department keep a register of GCP attendance and investigator CVs, including details of professional registration for clinically qualified staff. Staff are required to keep evidence of their own training history.

4. PROCEDURE

All new research staff shall attend mandatory training with the first 12 weeks.

Research staff are required to update their GCP training every 2 years.

5. RELATED DOCUMENTS & SOPS

HR21 Induction / Mandatory Training Policy
ICH-GCP - http://ichgcp.net/
UK Policy Framework for Health and Social Care Research (2017)