St George's University of London

St George's University Hospitals NHS
NHS Foundation Trust

Standard Operating Procedure (SOP)
Training Requirements for Clinical Research

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Signature of Authorisor			

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Researchers and their teams are responsible for checking the JREO website for the most recent version. They may print off this document for training and reference purposes.

SOP Chronology		
SOP Version Number:	**Reason for Change:**	**Author:**
V1.0	Original Version	Lucy Parker
V2.0	Updated with new Trust Logo and Foundation Trust	Nadia Azzouzi
V3.0	Update to title to provide overall guidance on training requirements. Update to policy on GCP and training requirements in line with HRA expectations	Subhir Bedi

Table of Contents	Page

1. Background

It is important to ensure and evidence that individual members of the research team have an appropriate level of awareness of the correct procedures, what those procedures entail and the importance of following them in respect to clinical research management. Research team members must be appropriately qualified by training, experience and education to undertake the responsibilities delegated to them.

Investigators and their teams must ensure that they are familiar with the requirements of Good Clinical Practice (GCP) and appropriate research management considerations, and that they maintain training records to show that all members of the trial team are "qualified by education, training and experience to perform his or her respective task(s)"(ICH GCP 2.8). In addition, the EU Clinical Trials Directive 2001/20/EC, EU Good Clinical Practice Directive 2005/28/EC and The Medicines for Human Use (Clinical Trials) Regulations 2004 and subsequent amendments require clinical trials to be conducted according to the principles of Good Clinical Practice (GCP).

Any training undertaken by researchers and their teams must also be carried out in conjunction with other St George's University of London (SGUL) and St George's University Hospitals NHS Foundation Trust (SGHFT) processes, procedures and policies. If any SGUL or SGHFT sponsored study is taking place at another site, the researchers must also be aware and follow local NHS Trust policies and procedures.

2. Joint Research and Enterprise Office (JREO) Policy

All JREO SOPs will be produced and approved in accordance with the JREO SOP on SOPs and must be used in conjunction with local NHS Trust and St George's policies and procedures.

The JREO acts as the representative of both St George's University of London (SGUL) and St George's University Hospitals NHS Foundation Trust (SGHFT). St George's will be the official name used on all SOPs to represent both institutions acting as Sponsor.

3. Scope

This Standard Operating Procedure (SOP) describes the training requirements for personnel involved in clinical research sponsored and or hosted within St George's.

4. Definitions

For general research management related acronyms used in this SOP please refer to "General Research Definitions" working practice document (JREOWPD0020).

5. Responsibilities

This SOP is to be followed by the Chief Investigator (CI), Principle Investigator (PI) and his or her research team.

The Sponsor is responsible for defining, and providing and or facilitating study specific training to all members of the research team.

6. Procedure

5.1 SOP specific Training

All staff should read and familiarise themselves with SOPs relavent to their current role and duties and this should be docmented within their training record.

5.2 GCP Training:

GCP training for all staff involved in research at the level commensurate with their involvement.

- For CTIMP and or Device trials (i.e. clinical trials that require MHRA approval), all members of staff (including the PI) should have undertaken GCP training prior to their involvement in the clinical trial.
  GCP training should be renewed every 3 years or after any significant change/update in GCP guidelines. Online "refreshers" courses are acceptable.
- For other types of interventional studies (i.e. surgical, high risk interventional research projects etc.) it is **recommended** researchers undertake appropriate GCP training prior to performing any study related activity.
- All staff undertaking research-related activities for non-interventional studies are encouraged to undertake some form of GCP training as part of their development, however this is not mandatory.

GCP Training should be through a recognised structured course which considers both UK and European Regulations. The National Institute of Health Research (NIHR) GCP course (either taught or on-line) is recommended.

5.3 Consent Training

ICH-GCP confirms that the Principal Investigator (PI) has overall responsibility for the consent process. However, other suitably qualified and trained professionals can take informed consent for the research study if the PI/Sponsor agrees. All personnel who wish to receive consent from subjects for research should complete consent training with the exceptions of focus groups,

self-completion questionnaires, surveys or use of anonymous data / tissue studies. This can be part of a GCP training course or standalone training. The NIHR provide both opportunities.

5.4 Study Specific Training:

It is the responsibility of the study sponsor to outline and provide and or facilitate study specific training for the research team.

It is the respnsibulity of the study PI and study team members to ensure individuals have recieved appropriate study level training relavent to their delegated duties.

All research team members are encouraged to attend sponsor visits to familiarise themselves with the study protocol and visit requirement, and to request additional training where relavent/ or where not provided.

5.5 Training Records:

Training records should be produced before the study/role starts and should be updated throughout the study / researchers employment.

Creation of a Training Record

All members of staff should create their own training record file (see suggested content in Appendix 1). This should include a copy of the current signed CV updated to include the current role. It is important to also include any study specific training such as study initiation visits or SOP training. If working on a Clinical Trial of an Investigational Medicinal Product (CTIMP) – then the record must also include the Good Clinical Practice (GCP) training undertaken.

Storing the Training Record

It is recognised that staff often take part in multiple research projects, and that storing several copies of the same document can be inefficient. In addition to an individual's own personal training record, for every project there should be a copy of the training record for relevant staff within the study/site file, or a file note stating where they are located.

With the Study File or Investigator Site File

A copy of the training record should be filed within the Investigator Site File in the relevant section along with an up to date signed CV.

Central Location

For instances where a research team is conducting multiple different studies, it is acceptable to store training records and CVs in a central file and refer to them (with agreement from the sponsor). All training records must be current, signed CVs should be dated (by hand or using a header/footer) and the records should include dates of training attended. A file note must be placed in the relevant section of each study file/ISF referring to the specific location of the relevant training records so that they can be easily located.

EDGE provides functionality for users to provide and update professional information including those related to training and development. Investigators and their research team members are encouraged to upload their training certificates and updated CVs onto their profiles.

A copy of the researchers current CV, GCP/consent certificate should be forwarded to the JREO to be filed within the electronic JREO file or an indication most recent versions can be viewed on EDGE. Updated versions should be provided periodically.

Updating the Training Record

It is the responsibility of individual members of staff to maintain their own training record. Training records should be reviewed by the Chief Investigator/Principle Investigator (study specific) and/ or line managers, during Performance Review (PR) (job competencies and continued professional development).

Archiving the Training Record

When a member of staff leaves post, they may want to take their training record file with them. A copy of their record should be made and kept in the Trial Master File (TMF – See JREOSOP0019 for TMF management) or site file with the date of leaving noted on the Staff delegation of duties & responsibilities log e.g. JREOLOG0004.

7. References

ICH on Good Clinical Practice
JREOLOG0004 Staff Delegation of duties & responsibilities log
JREODOC0011 CV Template
JREOSOP0019 TMF Management
JREOWPD0020 General Research Definitions
The Medicines for Human Use (Clinical Trials) Regulations 2004
EU directive on clinical trials (2001/20/EC)

EU Good Clinical Practice Directive 2005/28/EC

UK policy framework for health and social care research (v3.2, 10/10/2017)

MHRA & HRA Updated guidance on Good Clinical Practice (GCP) training (25/10/2017) https://www.hra.nhs.uk/about-us/news-updates/updated-guidance-good-clinical-practice-gcp-training/

7. Appendices

Appendix 1: Training Record (suggested)

An individual's training record should contain the following and the file should be reviewed annually by relevant PI (study specific) an or Line manager (general)

- Name and contact details
- Current Job Description and any previous job descriptions that are relevant to the current post. It is important to add the dates of these positions if not present in CV).
- Certificates of course attendance and agenda of courses/meetings (where relevant). These can be photocopies or originals.
- Current CV which demonstrates education, training, qualifications and experience to date.(see suggested CV template – JREODOC0011)
- Training record logs, both current and previous.
- Details of any other relevant training conducted not listed in the current CV.