St George's University Hospitals NHS
NHS Foundation Trust

Standard Operating Procedure (SOP)

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Signature of Authorisor			

Standard Operating Procedure (SOP)

Training Records

SOP Chronology		
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V1.0	Original Version	Lucy Parker
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Table of Contents	Page
1. Background	3
2. Joint Research and Enterprise Office (JREO) Policy	3
3. Scope	4
4. Definitions	4
4.1 Standard Operating Procedure (SOP)	4
4.2 Date	4
4.3 Effective Date	4
4.4 Review Date	4
5. Responsibilities	5
6. Procedures	5
6.1 Writing SOPs	5
6.2 Authorising SOPs	6
6.3 SOP review	6
6.4 SOP referencing	6
6.5 Distribution of SOPs	6
6.6 Version Control	7
7. References	7
8. Appendices	7
8.1 SOP template	8

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1. Background

Investigators and their teams must ensure that they are familiar with the requirements of Good Clinical Practice and that they maintain their own 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 (SGHT) processes, procedures and policies. If any SGUL or SGHT 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 (SGHT). St George's will be the official name used on all SOPs to represent both institutions acting as Sponsor.

3. Scope

This SOP will describe the process for the preparation, review and approval of all training records for staff working on studies sponsored by St George's.

4. Definitions

No applicable definitions for this SOP

5. Responsibilities

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

If the study is a Clinical Trial of an Investigational Medicinal Product (CTIMP), then all members of the research team must have had demonstrable Good Clinical Practice (GCP) training within the previous 2 years. This must be renewed every 2 years throughout the life of the study. However, the JREO recommends that all researchers have GCP training if possible.

6. Procedure

Training records should be produced before the study starts and should be updated throughout the life cycle of the study. An electronic copy of the signed CV of every research member of a study must be sent to the JREO when a new study is approved. These are filed on the ReDA online database, which should be kept updated. It remains the responsibility of the CI, and delegated to the local PI, not the JREO, to ensure that all staff are appropriately trained, however.

6.1 Creation of a Training Record

All members of staff should create their own training record file (see suggested content in Appendix One). This should include a copy of the current CV (no older than 2 years old) updated to include the current role and signed. 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.

6.2 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 or line manager annually, during Performance Review (PR). The Investigator should check the following for completeness:

- CV – signed and dated
- Current Job Description

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- Copies of certificates for any training undertaken that year including any conferences attended
- Meeting Agendas (if part of the meeting was used for training)

6.3 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 JREOPSOP0019 for TMF management) or site file with the date of leaving noted on the Staff delegation of duties & responsibilities log e.g. JREOLOG004.

7. References

ICH on Good Clinical Practice
JREOLOG0004 Staff Delegation of duties & responsibilities log
JREODOC0011 CV Template
JREOSOP0019 TMF Management
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

8. Appendices

Appendix 1: Training Record (suggested)

An individual's training record should contain the following and the file should be reviewed annually by the CI. This review should be documented (e.g. the CI could sign and date the training record)

- Name and contact details
- Current Job Description and any previous job descriptions which 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.

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- Details of any other relevant training conducted not listed in the current CV.

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