Standard Operating Procedure (SOP)
Training Requirements for Clinical Research

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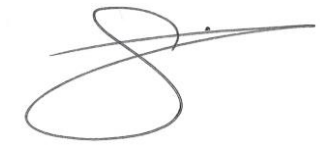
Signature of Authoriser			

This is a controlled document.

The master document is posted on the JRES website and any print-off will be classed as uncontrolled.

Researchers and their teams are responsible for checking the JRES 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
V4.0	Reflecting changes in JREO to JRES and job titles and minor changes to delegations of responsibilities. Also, insertion of associated JRES documents table. Updated references/links. Addition of Human Tissue training.	Ali Alshukry/Georgia Bullock

Associated JRES documents

SOPs	WPDs	Docs	LOGs
JRESGOVSOP0019 Preparation and Maintenance of the TMF	JRESWPD0023 General Research Definitions		JRESLOG0004 Staff Delegation of Duties Log JRESLOG0009 JRES SOP Reading Log

Contents

1. Background

ICH GCP states that 'each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task(s)' (ICH GCP 2.8).

It is important that all trial team members receive appropriate and documented training, to enable them to carry out their delegated trial-related tasks safely and correctly.

The Clinical Trials Regulations require CTIMPs to be conducted according to the principles of Good Clinical Practice (GCP). It is recommended that GCP principles are followed for non-CTIMPs and other research, although not a legal requirement.

Investigators and study team members must ensure that they are familiar with the requirements of GCP as well as with any legislation relevant to their research study. They must also be familiar with the study protocol and the procedures within this that they are responsible for.

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 (SGFT) processes, procedures and policies. If any SGUL or SGHFT sponsored study is taking place at another site, the researchers must also follow local NHS Trust policies and procedures.

2. Joint Research and Enterprise Services (JRES) Policy

All JRES SOPs will be produced and approved in accordance with the JRES SOP on SOPs and must be used in conjunction with local NHS Trust and University policies and procedures.

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

3. Scope

This SOP describes the training requirements for personnel involved in clinical research studies sponsored by, or hosted within, St George's.

4. Definitions

For general research-related acronyms used in this SOP, refer to General Research Definitions Working Practice Document (JRESWPD0023).

5. Responsibilities

This SOP is to be followed by the Chief Investigator (CI), Principal Investigator (PI) and their research team.

For CTIMPs, the Sponsor is responsible for defining, providing and/or facilitating study-specific training to all members of the research team/s.

6. Procedure

6.1 Training on SOPs

All research staff should read SOPs which are relevant to their role and duties and must ensure that they adhere to the procedures and processes described in the SOPs. The reading of SOPs should be documented as part of an individual's training record.

For CTIMPs sponsored by St George's, the assigned JRES Clinical Research Associate (CRA) will provide the trial team with the current versions of all relevant JRES SOPs and the reading of these will be documented on JRESLOG0009 (JRES SOP Reading Log).

For new or updated SOPs, the JRES will provide documented training on the procedures, where required, for JRES staff and study team staff.

Current versions of JRES SOPs and their related documents are available to research staff on the SGUL and SGHFT websites. Staff are responsible for ensuring that they refer to the current version of an SOP. Any queries on the processes described in an SOP should be directed to the Research Development and Governance Manager (RDGM) for further clarification.

6.2 GCP Training

For CTIMPs and Medical Device trials (ie: 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 at least every 3 years or after any significant change/update in GCP guidelines. Online "refresher" courses are acceptable.

For other types of interventional studies (ie: surgical, high risk interventional research projects), it is **recommended** that 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 completed through a recognised structured course. The National Institute of Health Research (NIHR) GCP courses (either online or classroom based) are recommended.

6.3 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 with the agreement of the PI and/or Sponsor.

All personnel who are to take consent from study participants should complete consent training, with the exception of those working on studies involving focus groups, self-completion questionnaires, surveys or the use of anonymous data or tissue. This training can be part of a GCP course or specific Informed Consent training. The NIHR provide both opportunities.

6.4 Human Tissue Act Training

All researchers working on studies which involve the collection and/or storage of human tissue samples, which fall under the remit of the Human Tissue Act 2004, should complete the Medical Research Council's 'Research and human tissue legislation' online training course or should

have completed appropriate alternative training. It is essential that they have a good understanding of the requirements of the Act and their responsibilities.

6.5 Study-Specific Training

It is the responsibility of the study Sponsor to ensure study-specific training is provided for the research team.

It is the responsibility of the study CI/PI and study team members to ensure individuals have recieved appropriate study training relevant to their delegated duties.

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

6.6 Training Records

Training records should be started before the study begins and should be updated throughout the study / researcher‘s employment.

6.7 Creation of a Training Record

All research staff should create their own training record file (see suggested content in Appendix 1). This should include:

- A copy of a current signed and dated CV, updated to include the current role.
- Any study-specific training such as SOP training or training on study procedures and assessments.
- GCP training evidence if working on a CTIMP.

6.8 Storing the Training Record

It is recognised that staff often work on 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.

<u>With the Study File or Investigator Site File</u>

A copy of a signed/dated CV, copies of relevant training certificates (eg: GCP) and training/attendance logs for any study-specific training should be filed in the ISF, for all study team members. CVs should be updated and signed every three years or re-signed if there are no updates required.

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 their location in a file note in the ISF for each study (with agreement from the Sponsor).

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 researcher's current signed and dated CV and GCP/consent certificate should be forwarded to the JRES to be filed within the electronic JRES file or a notification that the most recent versions can be viewed on EDGE.

6.9 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/Principal Investigator for the study-specific training and by line managers during an individual's Performance Review for personal development.

6.10 Archiving the Training Record

When a member of staff leaves their post, they may want to take their training record file with them. A copy of their record should be made and kept in the TMF or ISF with the date of leaving noted on the Staff Delegation of Duties Log.

7. References

ICH GCP.

NIHR GCP training:
https://www.nihr.ac.uk/health-and-care-professionals/learning-and-support/good-clinical-practice.htm

Informed Consent training:
https://globalhealthtrainingcentre.tghn.org/introduction-informed-consent/

Human Tissue training:

https://byglearning.com/mrcrsc-lms/course/index.php?categoryid=1

MHRA & HRA updated guidance on Good Clinical Practice (GCP) training (2017):

https://www.hra.nhs.uk/about-us/news-updates/updated-guidance-good-clinical-practice-gcp-training/

8. Appendices

8.1. Appendix 1: Training Record Contents (suggested)

- Name, job title 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 the CV.
- Certificates from courses where provided and agendas of courses/meetings (where relevant). These can be photocopies or originals.
- Current CV which demonstrates education, training, qualifications and experience to date and is signed/dated.
- A log of all training courses attended, both current and any relevant previous courses.
- Details of any other relevant training which has been completed.