Maintaining Training Records

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Version	Date	Reason for Change
Version 1.0	31 May 2007	
Version 2.0	24 Jun 2008	Annual review
Version 3.0	08 Feb 2010	Formation of Joint Research Office
Version 4.0	14 Jul 2011	Annual review
Version 5.0	03 Dec 2012	Annual review
Version 6.0	18 Feb 2015	Scheduled review
Version 7.0	25 Oct 2017	Scheduled review
Version 8.0	19 Oct 2020	Scheduled review Templates removed and administrative changes to SOP JRCO name change to RGIT.

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1. PURPOSE

This standard operating procedure (SOP) describes the process for maintaining training records within the RGIT and requirements for researchers conducting Imperial sponsored studies.

2. INTRODUCTION

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).

Staff working on research studies 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 E6 R2 2.8).

All training undertaken by the study's staff must be carried out in conjunction with our associated NHS Trusts and other Imperial College London or Imperial College Healthcare NHS Trust policies and procedures.

3. PROCEDURE

The following procedure will be used for maintaining training record files:

3.1. Creation of Training Record File

All members of staff should create their own training record file including the items listed in Appendix One. At the RGIT, some documents such as Documas and RGIT SOP read and acknowledged log will be filed separately in a central system. Refer to RGIT_SOP_011 SOP writing and review, this SOP which can be found on the SOP, Associated Documents & Templates page.

3.2. Updating of Training Record File

It is the responsibility of individual members of staff to maintain their own training record file on an ongoing basis.

Training records should be reviewed by the Chief/Principal Investigator or line manager annually, usually as part of the Personal Review and Development Plan (PRDP), i.e., appraisal review process. The Investigator/line manager should check the following for completeness and to identify possible training needs:

- Curriculum Vitae (CV) – signed and dated within the last two years (or when a new role is appointed)
- Job Description
- Copies of certificates for any training undertaken
- GCP certificate for staff involved in a clinical trial involving a Clinical Trial of an Investigational Medicinal Product (CTIMP) undertaken every 2 years.
- For staff working at the RGIT, GCP certificate for each staff updated every 2 years

For CTIMPs, training records will also be reviewed as part of the monitoring plan during the Site Initiation Visit (SIV).

3.3. Archiving of Training Record File

When an individual member of staff leaves post, they will want to take their training record file with them. A copy of the training record file should be taken and archived by the Chief Investigator (CI) with the date of leaving added to the CV and delegation log. The copies should be kept until they are no longer required in the event of an audit or inspection.

4. REFERENCES

ICH-GCP E6 R2 (2017)

EU directive on clinical trials (2001/20/EC)

EU Good Clinical Practice Directive 2005/28/EC

The Medicines for Human Use (Clinical Trials) Regulations 2004

5. APPENDICES

The following Appendices list the following Templates associated to this SOP which can be found on the SOP, Associated Documents & Templates page.

Appendix 1: Suggested Content of Training Record File

An individual's training record should contain the following and the file should be reviewed annually by the CI. Refer to section 3.2 above for how often these documents are updated.

- 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 they are not noted in the CV.
- Current CV, which demonstrates education, training, qualifications and experience to date.
- Training record logs, both current and previous training record logs. These should list all training that the individual has undertaken which shows that they are able to undertake the responsibilities delegated to them in a study.
- Certificates of course attendance and agenda of courses/meetings. These may be photocopies or originals.
- Details of any relevant training conducted prior to appointment, which may not listed in the current CV.

Appendix 2: Suggested CV template and Training Log template – RGIT_TEMP_036