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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.
Version 9.0	14 Jun 2024	3 year SOP review

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1. PURPOSE

This standard operating procedure (SOP) describes the process and requirements, as per good clinical practice (GCP), to maintain the training record folders of staff within the RGIT and other research staff conducting Imperial College sponsored studies.

2. INTRODUCTION

'In the GxP environment, training commonly falls into the following categories: mandatory training; role-based/role-specific training; needs-directed training' (RQA, 2015). In clinical settings, the mandatory training requirements are defined by the EU Clinical Trials Directive 2001/20/EC (Art. 4 & 6), EU Good Clinical Practice Directive 2005/28/EC (Art. 2), and the CTR (2004) as well as its subsequent amendments, from which all the principles of Good Clinical Practice (GCP) stem from.

In addition to the above, the training of all staff members who work in healthcare-related-research should be tailored differently depending on their role, the level of contact with patients/service-users, nature of their work, and level of responsibility. More precisely, all training of research staff must be carried out also in conjunction with the requirements by the associated NHS Trusts and other policies and procedures by the Imperial College of London and/or Imperial College Healthcare NHS Trust.

In light of the above, all staff working in social or healthcare research must ensure that they are familiar with the requirements of Good Clinical Practice and that they maintain their own training record folders, so that all members of the study team stay 'qualified by education, training and experience to perform his or her respective task(s)' throughout the course of the research study (ICH GCP E6 R2, 2.8).

3. PROCEDURE

In the following sections the local procedure for creating and maintaining research-staff training record folders will be detailed. Please note that a copy of this SOP and the related templates can be also downloaded from the RGIT website at the SOP, Associated Documents & Templates webpage.

3.1. Creating a 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 webpage.

3.2. Updating a 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 Annual Review Conversations (ARC). The Investigator/line manager should check the following for completeness and to identify possible training needs:

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• 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 a Training Record File

If an individual staff member leaving a post wishes to take their training record folder with them, their training record folder should be made a copy of and archived. The archiving procedure would fall under the responsibilities of the CI/PI and/or line manager, and the date of leaving should be annotated on the leaving staff member's CV as well as any delegation log where the role of the leaving staff member is contemplated. Finally, the above copies should be retained until this is required for audit or inspection purposes.

4. REFERENCES

ICH-GCP E6 R2 (2017).

EU directives on: clinical trials on IMPs 2001/20/EC & GMP 2005/28/EC.

UK Statutory Instrument N. 1031 (2004).

Management of the training and competency of personnel in GxP and research environments, Research Quality Association, (2015) ISBN 978-1-904610-36-6.

UK policy framework for health and social care research (cited on 27 Mar 2023).

GCP Certificate(s) (NIHR booking website) (cited on 27 Mar 2023).

CATO office website (cited on 27 Mar 2023).

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5. APPENDICES

The following appendices provide an explanatory list of all the items that should be comprised in the staff training record folders and additional reference to the RGIT_TEMP_036 for CV drafting. As previously mentioned, this SOP and its template can be also downloaded from the SOP, Associated Documents & Templates webpage (cited on 27 Mar 2023).

Appendix 1: Content of a Training Record File

A staff member's training record folder is expected to contain all the items listed below:

- A current job description and (possibly) any previous job descriptions that may be relevant to the current post: dates should be noted on these, if the CV does not list any dates.
- A current CV, detailing education, training, qualifications, and experience to date.
- The training record logs of both current and previous training: these should list all training that the individual has undertaken and prove their ability to undertake study related responsibilities.
- Additional details on any previous training that is relevant to the current appointment and may not be listed in the current CV.
- All training/course attendance certificates as well as training/meeting agendas (either as photocopies or originals).

As said, this content should be reviewed annually by the CI/PI and/or line manager, and this review should be in line with the relevant guidelines (as detailed in section 3.2) and comprise all necessary file updates.

Appendix 2: CV template and Training Log template – RGIT_TEMP_036

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