

ECTU Central Office SOP_AD_01: Creating and Maintaining Staff Training Records

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Authorship and Approval			
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Document Revision History		
Version No.	Effective Date	Summary of Revisions
1.0	28 Sep 2015	Initial creation
2.0	22 March 2016	Alterations after audit. 3.1 section name changed. Section 7 added to Section 3.2 and subsequent sections renumbered. Alteration to title of related WPD
3.0	07 May 2018	Minor alteration to wording in section 2. Reference to Training Record Location Log removed from section 3.1. Timeframe for establishing record removed from section 3.1. Alterations to the initial and ongoing review periods in section 3.3. Minor alteration to section 3.4. Document renumbered throughout. Document moved onto new SOP template
4.0	16 Nov 2020	SOP author has been changed. Purpose and scope updated to provide background and clarity. SOP has

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		<p>been updated extensively throughout to include details of what should be found in each section of the Training Record, removing the requirement for ECTU_WPD_AD_01. New supporting documentation produced.</p>
5.0	03 Nov 2022	<p>SOP has been transferred onto the new SOP template. Section 3 has been included which has had knock on effect to the numbering of subsequent sections.</p> <p>The following sections have been updated:</p> <p>4.2.1.1 – Updated to remove reference to clinical team.</p> <p>4.2.9.1 - updated to clarify that regularly means at least annually. Include QA review of Director and their direct reports annually.</p> <p>4.4.1 - updated to clarify the use of AD003.</p> <p>4.4.6 – updated to provide more detail on archiving.</p> <p>4.4.7 – created following update to 4.4.6.</p> <p>5.0 – updated to remove file path for each form, CV Template has been updated throughout, Form ID (AD-T006) also allocated.</p>

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1.0 PURPOSE

The Medicine for Human Use (Clinical Trials) Regulations 2004 (SI2004/1031) require clinical trials of investigational medicinal products (CTIMPS) to be conducted according to the principles of Good Clinical Practice (GCP). One of these principles, as laid down in the medicine for Human Use (Clinical Trials) Amended Regulations 2006 (SI2006/1928), is that:

‘Each individual involved in conducting a trial shall be qualified by education, training and experience to perform his tasks.’

This SOP describes the procedure for creation and maintenance of staff Training Records within Edinburgh Clinical Trials Unit (ECTU) for all staff in order to ensure standardisation and provide a process to demonstrate relevant and adequate training and experience of staff.

2.0 SCOPE

This SOP applies to all staff employed by the University of Edinburgh within Edinburgh Clinical Trials Unit (ECTU).

It defines the individual’s responsibilities and those of their line manager in relation to their Training Records.

3.0 RESPONSIBILITIES

It is the responsibility of each individual to ensure that their training record is kept up to date, current and reflects the training undertaken while in employment with ECTU.

Line managers are responsible for reviewing the training folder of their direct reports to ensure that appropriate training has been documented and any further training required is identified and provided.

QA will be responsible for reviewing training records as detailed in section 4.2.9.1 and for carrying out audits on others according to internal audit schedules.

4.0 PROCEDURE

4.1 Creating a Training Record

4.1.1 It is the responsibility of the employee to establish and maintain their Training Record. For new employees, establishing a Training Record is part of the induction process and is highlighted in the Induction pack.

4.1.2 The Training Record should be kept up to date and be available for audit and inspection purposes by ECTU and regulatory bodies as and when required.

4.2 Training Record Content

Each training record should contain a Training Record Index page detailing the sections that should be included.

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The following sections must be included in the Training Record:

4.2.1 Section 1: Current *curriculum vitae* (CV)

4.2.1.1 This section should contain a current CV providing a summary of the individual's education, training, qualifications and experience relating to their role. The CV must be reviewed and kept up to date (at least every 2 years), signed and dated by the employee and include their current roles.

Statisticians should ensure that their qualification certificate is included with their CV.

CV template is available on the shared drive.

4.2.2 Section 2: Current Job Description

4.2.2.1 A copy of the individual's current job description for the position held must be contained in this section. This must be signed and dated by employee.

4.2.3 Section 3: Previous Job Descriptions

4.2.3.1 If a job description changes and is superseded these should be marked as superseded and retained in this section.

4.2.4 Section 4: Training Log

4.2.4.1 The training Log (AD002) should be used to record all training undertaken by the employee. All training should be documented including those where certificates are provided.

4.2.5 Section 5: GCP certificates

4.2.5.1 GCP training certificates should be held here. The current certificate should be at the front of this section with previous certificates behind in date order.

4.2.5.2 GCP refresher training should be carried out every 2 years following initial GCP training.

4.2.6 Section 6: Other Certificates

4.2.6.1 Certificates of attendance for all other training courses where certificates are provided should be filed here in descending chronological order. This section should contain any certificates for courses attended whilst in employment.

4.2.7 Section 7: Research Passports

4.2.7.1 If required, this section should include documentation relating to Research Passports, Honorary Contracts and Letters of Access.

4.2.8 Section 8: SOP Receipts

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4.2.8.1 It is ECTU procedure that employees will provide QA with a receipt, via email, to confirm they have received and read the current version of an SOP as they are issued. Copies of these receipts can be kept in this section.

4.2.8.2 These receipts are also held electronically on the ECTU shared drive. 'Training Record Section 8 insert' should be added to this section, detailing where these are held as an alternative to a paper copy receipt.

4.2.9 Section 9: Training Record Review Log

4.2.9.1 Training Records should be reviewed at least annually by line manager to ensure completeness and to identify training needs. This may normally be done at annual performance review or appraisal and should be recorded within the Training Record using the Training Record Review Form (AD001). QA will review the Training Record for Director of the Unit and their direct reports on an annual basis.

4.2.9.2 Training Records may also be audited internally by QA. This audit will be recorded on AD001.

4.2.9.3 The reviews should include a list of any actions required and should be signed by the reviewer/auditor before being filed in the Training Records.

4.2.9.4 Training Records may also be audited during external audits and regulatory inspections.

4.3 Maintaining Training Records

4.3.1 Each individual is responsible for maintaining and updating the information held in their Training Record.

4.3.2 There should be a record of all training undertaken by the individual which supports and demonstrates their ability to undertake the tasks delegated to them.

4.4 Retention of Training Records

4.4.1 When an individual leaves ECTU, an ECTU Leavers Training Record Review Form (AD003) should be completed by their line manager. The original Training Record will be archived within ECTU. Should the individual wish to take their training record with them, a copy must be made and archived. The copy must be reviewed against the original and confirmed to be a complete and accurate copy. This should be documented on AD003.

4.4.2 It is the responsibility of the employee's Line Manager to ensure that a copy of the Training Record is retained when an employee leaves.

4.4.3 The date the Training Record is archived will be added to AD003.

4.4.4 The completed AD003 will be filed at the front of the Training Record.

4.4.5 A copy of completed AD003 will be provided to QA.

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- 4.4.6** QA will complete the Archive of Training Record in ECTU section of AD003 and will transfer documents held within training records, in full, to appropriate number of paper envelopes prior to archiving. Envelopes will be marked with individuals name, Training Record, Date left employment with ECTU and date archived.
- 4.4.7** Archived Training Records should be retained in ECTU archive until they are no longer required for audit or inspection purposes.

5.0 RELEVANT DOCUMENTS AND REFERENCES

The Medicines for Human Use (Clinical Trials) regulations 2004 (SI2004/1031) and Amendment Regulations 2006(SI2006/1928).

Standard Forms and Templates:

Training Record Review Form –AD001
ECTU Leavers Training Record Review/Archive - AD003
Record of Training Log – AD002
Training Record Index - AD004
Training Record Section 8 Insert
ECTU CV template- AD-T006

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