ECTU Central Office SOP ECTU_QA_02: Maintaining an Electronic Staff Training Record

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Authorship and Approval			
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Document Revision History		
Version No.	Effective Date	Summary of Revisions
1.0	15 Aug 2024	Initial creation
2.0	28 Oct 2026	Updated section 4.1. Sections in 4.2 have been updated to reflect current processes.

1.0 PURPOSE

The purpose of this SOP is to provide instruction and guidance to the Edinburgh Clinical Trials Unit (ECTU) staff on the use of electronically maintaining staff records using the REDCap Database.

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 electronic training records.

3.0 RESPONSIBILITIES

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

Line managers are responsible for reviewing the training record of their direct reports to ensure that appropriate training has been documented and any further training required is identified and provided. Annual reviews should be conducted at a minimum.

QA will be responsible for reviewing training records and for carrying out audits according to internal audit schedules.

4.0 PROCEDURE

A training record for all ECTU staff members will be created by the QA Manager or designee. For those who do not have a REDCap account, the QA Manager or designee will request access from the REDCap Administrator (Data Managers) or designee.

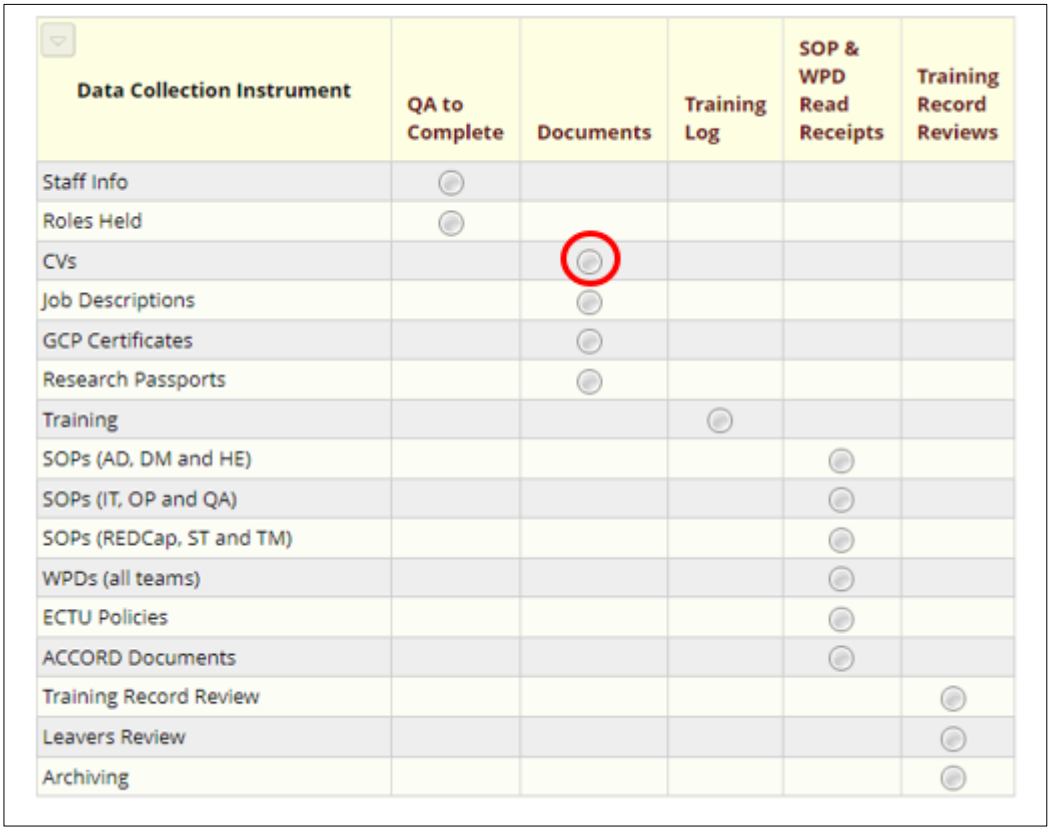
4.1 Logging into REDCap Database

- Login to the REDCap database using the assigned login details. During an external audit access to training records will be restricted for staff who are included in the audit. Staff members will be informed of this action prior to the audit. Access will only be restricted for the duration of an audit and any document requests thereafter will be shared with the external auditors on an ad-hoc basis by the QA Manager. If necessary, auditors can be granted access to review any corrective and preventative actions as per the audit report following the details mentioned in this section, and for the least amount of time that is necessary for review.

- Once logged in, on the left-hand side, select “Record Status Dashboard”



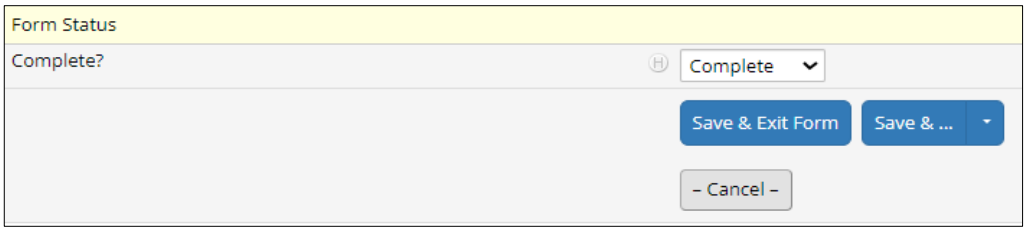
- The staff name will be displayed on the right-hand side of the screen. Once the name is selected the Record Home Page will be displayed, as shown below.



4.2 Updating Sections of the Training Record

4.2.1 Each section of the Training Record will be updated as detailed below. Select the option by clicking on the circular button (an example has been highlighted in red above) to update the respective section of the training folder.

4.2.2. Once the section has been completed, set the form status to complete, and then select ‘Save & Exit Form’. Omitting the ‘Save & Exit Form’ in any of the sections will result in losing the changes that were made.



4.2.3 The circle corresponding to the section will be green to indicate completed records. Selecting any other option will mark the record as red indicating an 'incomplete/ unverified' section. Selecting the cancel option, or the browser's back button, will return the user to the Record Home Page without saving the changes.

4.2.4 All sections under 'Staff Info' will be completed by the QA Manager or designee

4.2.5 The below sections will be completed by the staff member-

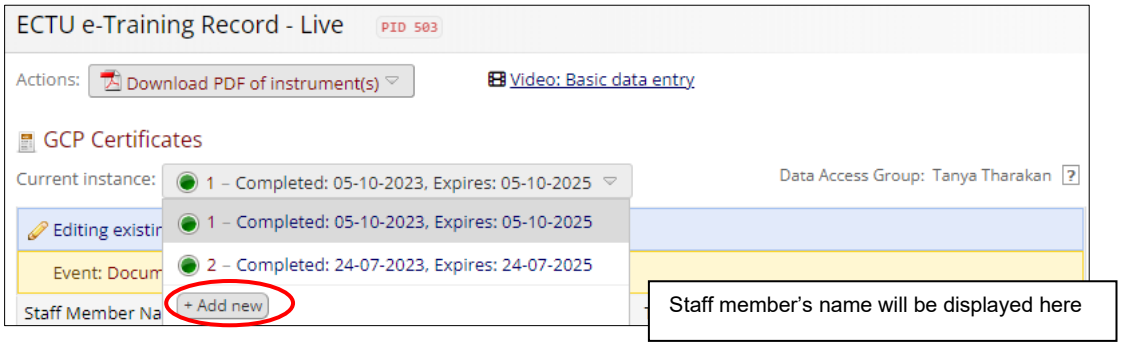
- Roles Held: Under the title 'Staff Role'
  - Select the designation of the staff member by using the drop-down list
  - Select the start date in the specified format by selecting the calendar option. (The start date is the date the staff member started their role within ECTU)
  - The End/ Leaving date will be completed, if applicable (this date indicates the last working date within ECTU)

- CVs: Under the title 'CV'
  Upload the current version of the CV in the ECTU QA004 CV Template format (see section 5).
  The CV should be electronically signed by the individual using Adobe. Wet signatures can be accepted in exceptional circumstances.
  - Select the option 'I confirm this CV is accurate and up to date as of the date of upload.'
  - Enter the date of upload or select the option 'Today', if applicable.
  - The CV should be renewed and added to the training record every two years.

- Job Descriptions: Under the title 'Job Description'
  - Upload the most recent version of your job description.
  - The job description should be electronically signed by the individual using Adobe. Wet signatures can be accepted in exceptional circumstances.
  - Select the role associated with this job description by using the drop-down list
  - Enter the date of upload or select the option 'Today', if applicable.
  - Select the checkbox 'I acknowledge that this document reflects my current roles and responsibilities'.
  - The job description should be updated only if there is a change to the responsibilities or role.

- GCP Certificates: Under the title 'GCP Certificates'
  - Upload your most recent ICH GCP E6(R3) certificate

Enter the date of completion or select the option of 'Today' if applicable. The GCP certificate should be renewed and added to the training record every two years. There are recommended virtual (NIHR) and in-person courses available (ECRF). See section 5.When uploading a new GCP certificate, **do not delete the previous copy**Select the '+Add new' option at the top of the page,



- Research Passports: This section applies to Research Passports which can be either Letters of Access or Honorary Contracts depending on the staff role and involvement with participant data. Under the title 'Research Passport' –
    - Select the correct option for whether the role requires the document
    - If required,
        - Select the applicable document from the drop-down list
        - Enter the date of issue/ use the calendar date entry option
        - Upload the relevant document(s)
        - Enter the date of expiry, or if applicable, check the box stating that the research passport does not have an expiry date
    - If not required, no further action is needed on this page. The individual can mark the page as complete and save the record.

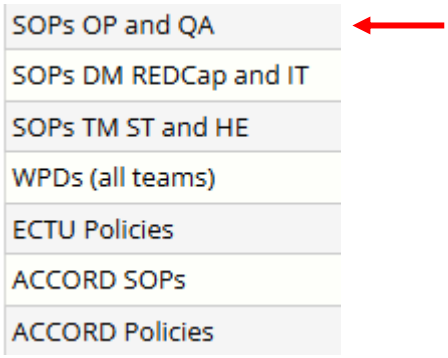
- Training: Under the title 'Training Log', for every individual training that has been completed -
    - Enter the date of issue/ use the calendar date entry option
    - Select the mode of training
        - Workshop/ Seminar (for example, the Edinburgh Clinical Trial Management Course)
        - Lecture/ Formal Session
        - Online learning module (for example, University of Edinburgh courses/ Usher Training Matrix courses)
        - Internal training on work task/s (for example, training provided by ECTU line managers, senior colleagues etc.)
        - Other (any other training that does not fall under the remit of the above options)

- SOP Read Receipts: ECTU and ACCORD documents are contained within the titles shown below. Select the circular button to go to the required section, and complete the document read receipt -
    - SOPs (OP and QA)

- SOPs (DM, REDCap and IT)
- SOPs (TM, ST and HE)
- WPDs (All teams)
- ECTU Policies
- ACCORD SOPS
- ACCORD Policies

An example for the read receipt process is shown below,

1) Select the correct group.

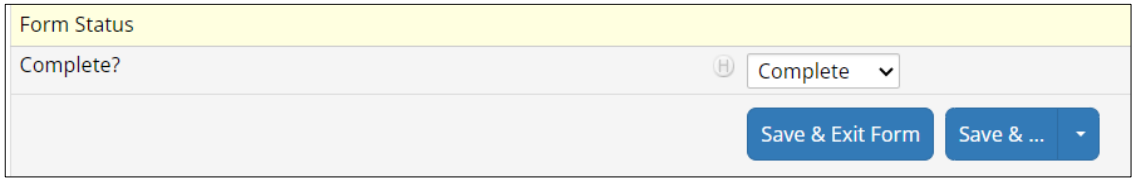


2) Select the option “I confirm I have read and understood”, to read receipt the SOP.



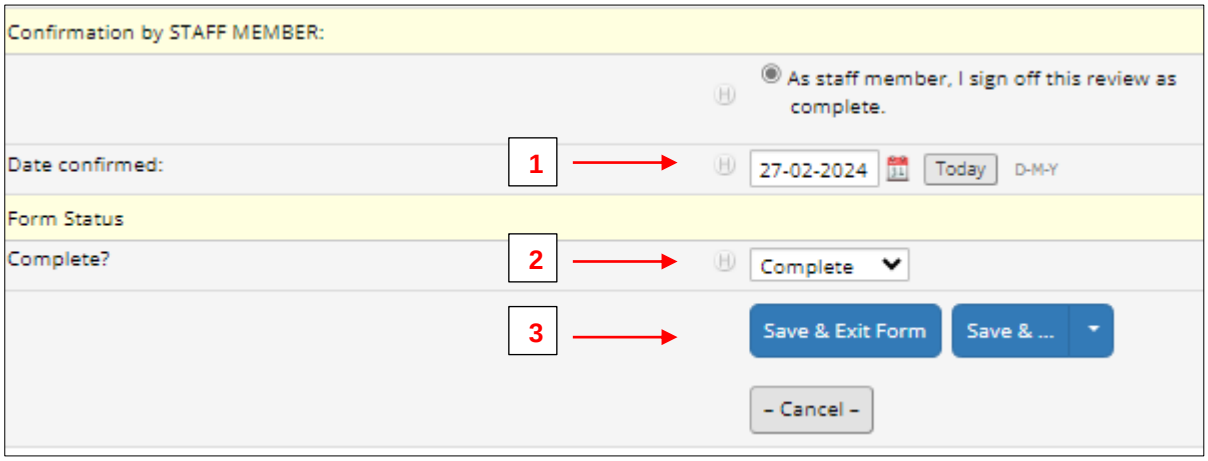
Where the SOP is not applicable to the role, the section can be marked as ‘N/A’. Staff should ensure this has been approved by their line manager or the QA Manager before marking the SOP as not applicable.

3) Complete the “Form Status”, by selecting Complete (if applicable) from the drop-down list, Save & Exit Form. **If the ‘Save & Exit Form’ is not selected, the read receipt will not be recorded.**



4.2.6 Training Record Review: The actions for completing a training record review form are detailed in ECTU_WPD_QA_W1 Line Manager and QA Review of Electronic Staff Training Record.

The staff member will receive an automated email indicating that a review has taken place and by whom. The pending actions must be completed as indicated in the review, if applicable, or if there are no further tasks to be completed, update the "Confirmation by STAFF MEMBER" section, select the "Form Status" as 'complete', the "Save & Exit Form".



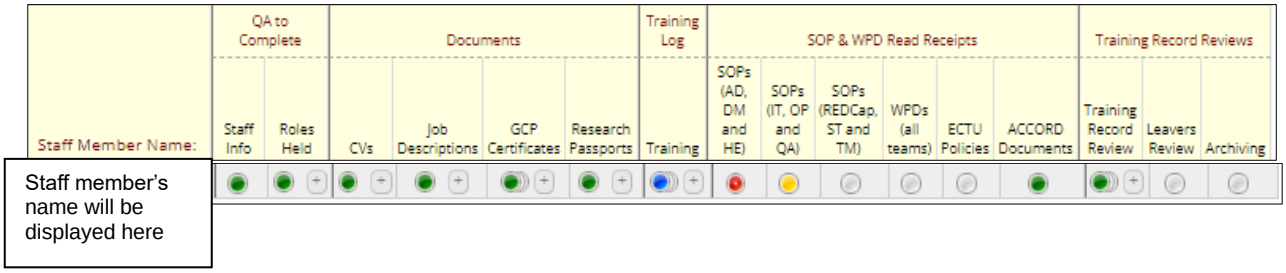
4.2.7 The sections for Training Record Review, Leavers' Review and Archiving will be initiated and completed by the line manager or QA Manager where applicable, as detailed in ECTU_WPD_QA_W1 Line Manager and QA Review of Electronic Staff Training Record

4.2.8 Ensure all sections with changes are saved, before logging out from the REDCap Database.

Note: A prolonged period of inactivity will trigger an automatic exit from the database, and any unsaved changes will be lost.

4.2.9 Sections that have been updated, and saved as

- 'Complete' will be green,
- 'Incomplete' will be red,
- 'Unverified' will be yellow, and
- Mixed record statuses will be in blue.



5.0 RELEVANT DOCUMENTS AND REFERENCES

On ECTU Website

- ECTU_WPD_QA_W1 Line Manager and QA Review of Electronic Staff Training Record
- QA004 CV Template

ECTU DataStore (ECT Unit\SOPs\Finalised SOP and WPD\QA\Supporting Documents and Templates\Current\pdf)

- ECTU e-Training User Guide

Others

- NIHR GCP courses: https://learn.nihr.ac.uk
- Edinburgh Clinical Research Facility (ECRF) GCP courses: https://clinical-research-facility.ed.ac.uk/core-services/education/courses-and-events.

ECTU_SOP_QA_02 Maintaining an Electronic Staff Training Record v2.0 and QA004 CV template

Final Audit Report 2026-09-28

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By:	Tanya Tharakan (tanya.tharakan@ed.ac.uk)
Status:	Signed
Transaction ID:	CBJCHBCAABAA67WqSFUZPEneCuSKqT4c8ARj-vf6PMZf

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