

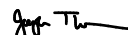





## ECTU Central Office SOP ECTU\_QA\_02: Maintaining an Electronic Staff Training Record

Version No:	1.0
Issue Date:	12 Jul 2024
Effective Date:	15 Aug 2024

Authorship and Approval			
Name and Designation	Author/Reviewer /Approval/ Authorisation	Date	Signature
Tanya Tharakan, QA Manager	Author	12-Jul-2024	 <small>Tanya Tharakan (Jul 12, 2024 14:23 GMT+1)</small>
Lynne McGillivray Business and QA Administrator	Reviewer	12-Jul-2024	
Joyce Thomson Chief Operating Officer	Approver	12-Jul-2024	 <small>Joyce Thomson (Jul 12, 2024 13:35 GMT+1)</small>
Tanya Tharakan QA Manager	QA Authorisation	12-Jul-2024	 <small>Tanya Tharakan (Jul 12, 2024 14:23 GMT+1)</small>

Document Revision History		
Version No.	Effective Date	Summary of Revisions
1.0	15 Aug 2024	Initial creation

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## 1.0 PURPOSE

This SOP is to be applied in conjunction with ECTU SOP AD 01 Creating and Maintaining Staff Records.

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

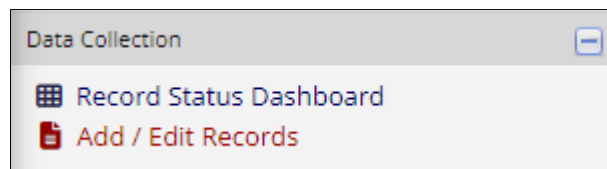
QA will be responsible for reviewing training records and for carrying out audits according to internal audit schedules.

## 4.0 PROCEDURE

A training record for all ECTU staff members will be created by QA. For those who do not have an account, QA 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.
- Once logged in, on the left-hand side, select "Record Status Dashboard"



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- 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 seen below.

Data Collection Instrument	QA to Complete	Documents	Training Log	SOP & WPD Read Receipts	Training Record Reviews
Staff Info	<input type="radio"/>				
Roles Held	<input type="radio"/>				
CVs		<input checked="" type="radio"/>			
Job Descriptions		<input type="radio"/>			
GCP Certificates		<input type="radio"/>			
Research Passports		<input type="radio"/>			
Training			<input type="radio"/>		
SOPs (AD, DM and HE)				<input type="radio"/>	
SOPs (IT, OP and QA)				<input type="radio"/>	
SOPs (REDCap, ST and TM)				<input type="radio"/>	
WPDs (all teams)				<input type="radio"/>	
ECTU Policies				<input type="radio"/>	
ACCORD Documents				<input type="radio"/>	
Training Record Review					<input type="radio"/>
Leavers Review					<input type="radio"/>
Archiving					<input type="radio"/>

## 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'.

Form Status

Complete? ⓘ Complete ▾

Save & Exit Form
Save & ... ▾

- Cancel -

- 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'

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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** The below sections will be completed by QA in the first instance, and maintained by the staff member thereafter-

- Staff Info: Under the title 'Staff Information' enter
  - The staff email address
  - The relevant departments that the staff belongs to
  - Name of the current line manager
  - Email address of the line manager
  
- SOP read receipts as per the SOPs Read by Individuals 2024 tracker.

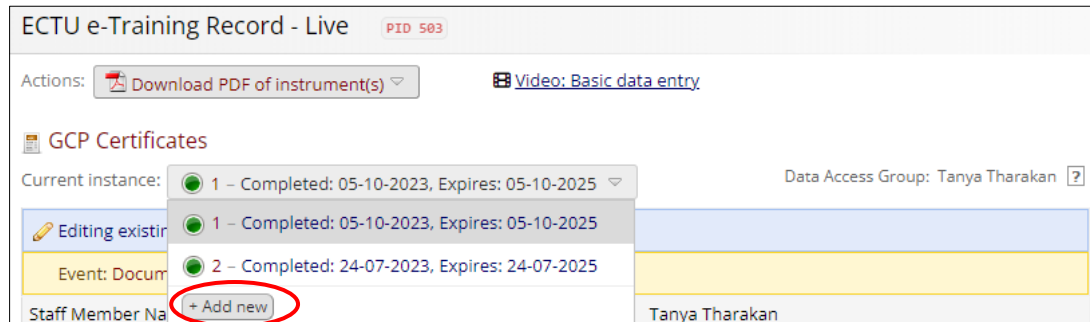
**4.2.5** The below sections will be completed by the staff member-

- 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 your current version of the CV, preferable in the format AD-T006 CV Template. If the individual's CV contains all the relevant sections pertaining to the format, this document can be uploaded.  
  
The CV should either be electronically or wet signed, and dated by the individual
  - 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.
  
- Job Descriptions: Under the title 'Job Description'
  - Upload the most recent version of your job description.
  - The job description should either be electronically or wet signed, and dated by the individual.
  - 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'.
  
- GCP Certificates: Under the title 'GCP Certificates'
  - Upload your most recent GCP certificate
  - Enter the date of completion, or select the option of 'Today' if applicable. The expiry date for your certificate will be automatically calculated.
  - When uploading a new GCP certificate, **do not delete the previous copy.**

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- Select the '+Add new' option at the top of the page,




The screenshot shows the 'ECTU e-Training Record - Live' interface. At the top, there are actions like 'Download PDF of instrument(s)' and a video link 'Basic data entry'. Below this is a section for 'GCP Certificates'. A table lists two instances: Instance 1 (Completed: 05-10-2023, Expires: 05-10-2025) and Instance 2 (Completed: 24-07-2023, Expires: 24-07-2025). The 'Staff Member Name' column shows 'Tanya Tharakan'. A red circle highlights the '+ Add new' button at the bottom of the table.

- Research Passports: This section applies to Research Passports/ Letters of Access/ Honorary Contracts. 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 Trials 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)
    - Other (any other training that does not fall under the remit of the above options)
- ECTU and ACCORD documents are under the titles seen below. Select the circular button to go to the required section, and complete the read receipt -
  - SOPs (AD, OP and QA)
  - SOPs (DM, REDCap and IT)
  - SOPs (TM, ST and HE)
  - WPDs (All teams)
  - ECTU Policies
  - ACCORD SOPS
  - ACCORD Policies

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An example for the read receipt process is shown below,

- 1) Select the correct group.

SOPs AD OP and QA				<input checked="" type="radio"/>	
SOPs DM REDCap and IT				<input type="radio"/>	
SOPs TM ST and HE				<input type="radio"/>	
WPDs (all teams)				<input type="radio"/>	
ECTU Policies				<input type="radio"/>	
ACCORD SOPs				<input type="radio"/>	
ACCORD Policies				<input type="radio"/>	

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

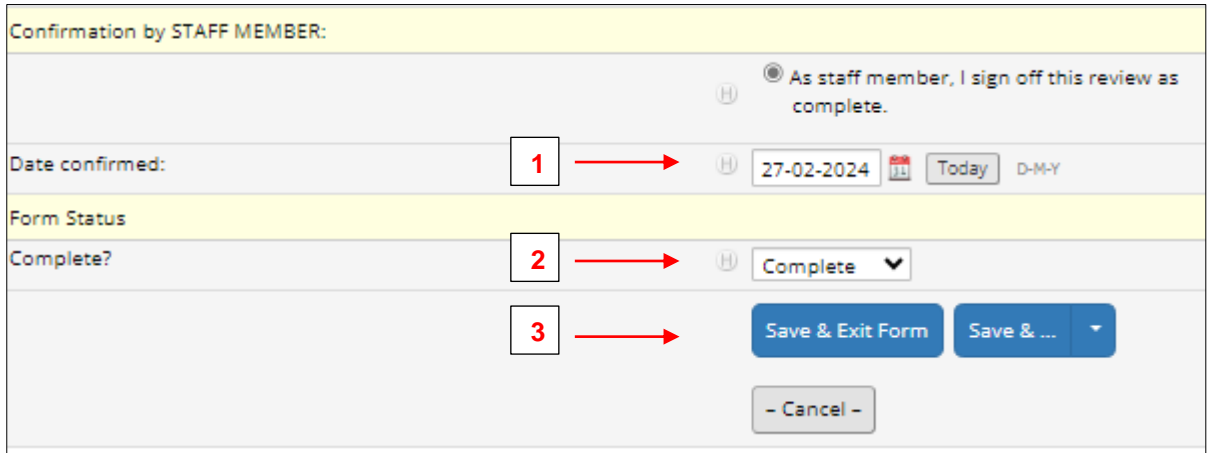
AD SOPs	
ECTU_SOP_AD_01 Creating and Maintaining Staff Training Records AD_01, Version 5.0, effective date 03 Nov 2022	<input checked="" type="radio"/> I confirm I have read and understood. ▾
OP SOPs	
ECTU_SOP_OP_01 Development and Management of Policies, SOPs and WPDs OP_01, Version 7.0, effective date 14 Mar 2024	<input checked="" type="radio"/> I confirm I have read and understood. ▾

- 3) Complete the “Form Status”, by selecting Complete from the drop-down list, Save& Exit Form. **Please note, if you do not complete this step, your read receipt will not be recorded.**

Form Status	
Complete?	<input checked="" type="radio"/> Complete ▾
<input type="button" value="Save &amp; Exit Form"/> <input type="button" value="Save &amp; ... ▾"/>	

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**4.2.6 Training Record Review:** 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 below sections will be completed by the line manager as detailed in ECTU\_WPD\_QA\_W1 Line Manager and QA Review of Electronic Staff Training Record

- Training Record Review
- Leavers Review
- Archiving

**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.

Staff Member Name:	QA to Complete		Documents				Training Log	SOP & WPD Read Receipts					Training Record Reviews			
	Staff Info	Roles Held	CVs	Job Descriptions	GCP Certificates	Research Passports	Training	SOPs (AD, DM and HE)	SOPs (IT, OP and QA)	SOPs (REDCap, ST and TM)	WPDs (all teams)	ECTU Policies	ACCORD Documents	Training Record Review	Leavers Review	Archiving
Tanya Tharakan	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●

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## 5.0 RELEVANT DOCUMENTS AND REFERENCES

### [On ECTU Website](#)

- ECTU SOP AD 01 Creating and Maintaining Staff Records.
- ECTU\_WPD\_QA\_W1 Line Manager and QA Review of Electronic Staff Training Record
- AD-T006 CV Template

### [On ECTU Shared Drive](#)

- ECTU e-Training User Guide

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# ECTU\_SOP\_QA\_02 Maintaining an Electronic Staff Training Record v1.0 and other documents

Final Audit Report

2024-07-12

Created:	2024-07-12 (British Summer Time)
By:	Tanya Tharakan (tanya.tharakan@ed.ac.uk)
Status:	Signed
Transaction ID:	CBJCHBCAABAA6WZIK6NocLhGsl_SFpD_WADf71BfdpqP

## "ECTU\_SOP\_QA\_02 Maintaining an Electronic Staff Training Record v1.0 and other documents" History

-  Document created by Tanya Tharakan (tanya.tharakan@ed.ac.uk)  
2024-07-12 - 12:38:17 GMT+1- IP address: 192.41.114.230
-  Document emailed to Joyce Thomson (joyce.thomson@ed.ac.uk) for signature  
2024-07-12 - 12:47:09 GMT+1
-  Document emailed to Lynne McGillivray (lynne.mcgillivray@ed.ac.uk) for signature  
2024-07-12 - 12:47:09 GMT+1
-  Document emailed to Tanya Tharakan (tanya.tharakan@ed.ac.uk) for signature  
2024-07-12 - 12:47:09 GMT+1
-  Email viewed by Lynne McGillivray (lynne.mcgillivray@ed.ac.uk)  
2024-07-12 - 13:09:41 GMT+1- IP address: 192.41.114.226
-  Document e-signed by Lynne McGillivray (lynne.mcgillivray@ed.ac.uk)  
Signature Date: 2024-07-12 - 13:10:20 GMT+1 - Time Source: server- IP address: 192.41.114.226
-  Email viewed by Joyce Thomson (joyce.thomson@ed.ac.uk)  
2024-07-12 - 13:35:04 GMT+1- IP address: 104.47.11.126
-  Document e-signed by Joyce Thomson (joyce.thomson@ed.ac.uk)  
Signature Date: 2024-07-12 - 13:35:47 GMT+1 - Time Source: server- IP address: 94.14.215.249
-  Document e-signed by Tanya Tharakan (tanya.tharakan@ed.ac.uk)  
E-signature hosted by Tanya Tharakan (tanya.tharakan@ed.ac.uk)  
Signature Date: 2024-07-12 - 14:23:24 GMT+1 - Time Source: server- IP address: 192.41.114.230- Signature captured from device with phone number XXXXXXXX5931

✔ Agreement completed.

2024-07-12 - 14:23:24 GMT+1