ECTU Central Office WPD_ST_W1: General Guidelines

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Document Revision History		
Version No.	Effective Date	Summary of Revisions
1.0	13 Mar 2017	New Document
2.0	12 Mar 2018	Changes to SAS Installation Instructions in sections 2.3 and 2.3.1
3.0	28 Aug 2020	Updated at scheduled review. Document moved to new WPD template. With the exception of section 2.3 where more substantial amendments were made, minor changes were made throughout the document.

4.0	25 Nov 2022	Changes made to section 2.1.2 regarding access to study database and 'unblinded' folder and update reference to Data Management and Programming Team. Changes made to section 2.1.3 regarding procedures for new starts. A new section 2.2.2 was added regarding a Letter of Access. Some updates were made to section 2.2.4 regarding where to access GCP training and importance of completing the training at an early stage. Some links in section 3 did not work so these have been updated. Section 2.1.4 has been moved to section 2.3 to keep everything SAS related together. Section 2.3.4 updated to reference Data Management and Programming Team.
5.0	20 Jan 2025	Updated wording in section 2.1.3 to cover WPDs. Section 2.2.1 now covers electronic training records instead of paper-training records which are now obsolete. Updated wording in section 2.3.3 to say that any error messages which occur at the SAS IQ or OQ validation should be investigated. Changes to section 2.3.4 to cover REDCap processes. Section 2.3.5 now covers optional ODBC connection (via VPN if working from home)

1. INTRODUCTION

This Working Practice Document (WPD) provides general guidance on the arrangements to be made for new employees within the Statistics Team at the Edinburgh Clinical Trials Unit (ECTU). These guidelines are specific to Statisticians. General guidance for all new employees within ECTU is provided in the ECTU Induction Pack and ECTU POL03: ECTU Staff Induction and Training Policy.

2. INSTRUCTIONS AND GUIDANCE

2.1 Staff Arriving

2.1.1 New starts need to gain access to the ECTU shared drives and access should be requested through their line manager. Once approved, access needs to be granted via the Information Services (IS) helpline. See section 3 for contact details. Once access has been permitted, follow the instructions on the IS webpage (see section 3 for the relevant link) to map the ECTU shared drive onto the new start's network drive.

2.1.2 With guidance from their line manager (or in some instances, the study senior statistician), the new start should arrange access to the appropriate current project folders, organising unblinded access where necessary. The ECTU Data Management and Programming Team control access to the study database. The ECTU stats team leads control access to the 'Unblinded' folder. Requests must be made to gain access to both the study database and the 'Unblinded' folder. Please refer to 'ECTU_SOP_ST_07 Defining Data Access Requirements for Blinded and Unblinded Statisticians' for more details.

2.1.3 All ECTU Standard Operating Practices (SOPs) and Working Practice Documents (WPDs) relevant to the Statistics Team (ST) can be found in on the ECTU and ACCORD website (see section 3) The statistics team also has an ECTU Core SOP Read Receipt form and can be used as a guide for what SOPs and WPDs are to be read. This form will be provided by the QA Manager or delegate during QA induction. Study specific templates are available on the shared drive (section 3). QA or delegate will ensure that the new employee is given read only access to this folder and the Business Team will add the new employee to the ECTU mailing list. The new start/ line manager should arrange a meeting with QA (ideally within the first week of employment) to discuss SOPs, training records and anything else important to their role.

2.2 Training and Guidance

2.2.1 The new start's line manager should ensure that QA is informed of the new employee's start date so that an electronic staff training record can be arranged. Instructions on maintaining a staff training record will be provided at the QA induction and can be found in ' 'ECTU_SOP_QA_02 Maintaining an Electronic Staff Training Record'

2.2.2 The new start's line manager should ensure that a Letter of Access prior to the new start handling patient data (identifiable or anonymised data) has been obtained.

2.2.3 Each Statistician should add a copy of the certificate from their relevant undergraduate degree, MSc or PhD qualification in statistics to their online training record, ECTU_SOP_AD_01 Creating and Maintaining Staff Training records.

2.2.4 Good Clinical Practice (GCP) training should be completed as soon as possible after beginning employment at ECTU. Failure to complete this training may result in delays to any Clinical Trials of Investigational Medicinal Products (CTIMP) trials work that has been assigned to the new start. Links to GCP courses (in-person or online) are provided in section 3. Each Statistician is responsible for ensuring that their GCP certificate is up to date, although QA sends out a reminder before it is due to expire. Further information can be found in the 'ECTU POL03 Staff Training and Induction Policy'.

2.2.5 Each Statistician should familiarise themselves with the 'E9 Statistical Principles for Clinical Trials' as part of the Efficacy Guidelines from the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), and the biostatistics guidelines from the European Medicines Agency (EMA). The relevant website links can be found in section 3.

2.2.6 Each Statistician should familiarise themselves with relevant guidance in relation to their specific trials and role (e.g. trial design guidance relating to the therapeutic area of the trial and specific statistical guidance on for example, missing data, non-inferiority margin, switching between superiority and non-inferiority, small populations and adjustment of baseline covariates). It is not necessary to attend formal training but if training is attended it should be documented in the training record. It is the responsibility of each Statistician to read relevant guidance and share best practice.

2.3 SAS – Installation and Usage

2.3.1 Prior to running any analysis on CTIMP trials, the new start should ensure that they have SAS installed on their computer (also refer to section 3 'IS SAS for Staff and Students'). Some employees may wish to download additional statistical software, such as R and/or Stata. If this is the case, then the new start should discuss this with their line manager.

2.3.2 SAS can be installed by either sending a request to the IS helpline to install a copy of the software, or by downloading SAS through the University's application catalogue (see section 3 for the link to 'Install Applications').

2.3.3 After installation, run the SAS Operational Qualification (SAS OQ) and the SAS Install Qualification (SAS IQ) tools. These tools will require an output directory. Documentation produced from these tools should be saved in the ECTU shared drive

(ECT Unit/1. ECTU FILING SYSTEM – AMENDED 2010/ECTU Operational/Statistics Team (ST)/System validation) in a folder with the user's name. There should ideally be no errors in the output files however, any errors presented should be investigated. If they are unavoidable and do not affect the reliability of the software then a file note should be written. This should be filed along with the OQ and IQ output in the appropriate user folder.

2.3.4 Many clinical trials run through the ECTU have databases created using REDCap. The new start (or designee) will be required to send an email to the ECTU Data Management and Programming Team to order to set up a REDCap account and grant appropriate permissions to access and download relevant study data via REDCap.

2.3.5 Some trials may require an Open Database Connectivity (ODBC) connection to be set up to link to the relevant project(s) within the ECTU database. If appropriate, the ECTU Data Management and Programming Team will provide the statistician with a project and server name and following steps should be taken to access the database:

- Start Menu -> Control Panel -> System and Security -> Administrative Tools
- Double click on ODBC Data Sources (64-bit) – this will bring up the ODBC Data Source Administrator
- In the ODBC Data Source Administrator, click 'Add'
- Go to the bottom of the list and click on 'SQL server', and then 'Finish'
- Type a project name in the 'Name' box (e.g. TOPPIC)
- Complete the 'Description' box
- Type the server name (most of the studies will be on igmm-store.igmm.ed.ac.uk) in the 'Server' box and click 'Next' twice
- Tick the 'Change default database' box and choose the appropriate database from the list. Click 'Next' and then 'Finish'

You can check that the set-up is OK by clicking 'Test data source' and then clicking 'Ok' twice. The connection should now be set-up. Note that the new statistician will required to set up a VPN to connect to the ODBC database if trying to access from home.

2.4 Version Control and Naming Conventions

Version control and naming conventions should be in line with ACCORD guidelines as set out in ACCORD SOP QA008 Document Version Control. See section three for a link to the ACCORD website.

3. RELEVANT DOCUMENTS AND REFERENCES

ECTU Website

- ECTU_SOP_ST_07 Defining Data Access Requirements for Blinded and Unblinded Statistician
- ECTU_SOP_AD_01 Creating and Maintaining Staff Training records
- ECTU_SOP_QA_02 Maintaining an Electronic Staff Training Record
- ECTU Central Office POL03: ECTU Staff Induction and Training Policy'

ECTU Templates on the Shared Drive

Others

- ACCORD website
- Edinburgh Clinical Research Facility: https://clinical-research-facility.ed.ac.uk/core-services/education/courses-and-events
- NIHR GCP: https://www.nihr.ac.uk/health-and-care-professionals/learning-and-support/good-clinical-practice.htm.
- National Institute for Health and Care Research: https://www.learn.nihr.ac.uk
- EMA Guidelines
- ICH Efficacy Guidelines: https://www.ich.org/page/efficacy-guidelines
- IS Contact details: Tel: 0131 651 5151, Email: IS.Helpline@ed.ac.uk or access through the self-service portal in myed.ed.ac.uk
- IS Connect to University file storage in Windows: https://www.ed.ac.uk/information-services/computing/desktop-personal/connect-uni- file-storage/windows
- IS SAS for Staff and Students**:** https://www.ed.ac.uk/information-services/computing/desktop-personal/software/main- software-deals/sas
- IS Installing Applications: https://www.ed.ac.uk/information-services/computing/desktop-personal/supported/windows- 10/training/software-center
- QA inbox details**:** qa.ectu@ed.ac.uk

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