

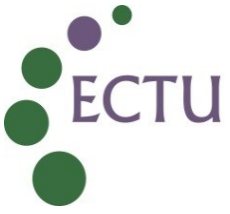
ECTU Central Office WPD_ST_W1: General Guidelines

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Caroline Garth, QA Manager	QA Authorisation	21 Nov 2022	See retained approval email dated 21 Nov 2022

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	01 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

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		moved to section 2.3 to keep everything SAS related together. Section 2.3.4 updated to reference Data Management and Programming Team.
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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 Trial Unit (ECTU). These guidelines are specific to Statisticians. General guidance for all new employees within ECTU is provided in the ECTU Induction Pack.

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 your 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) relevant to the Statistics Team (ST) can be found in the SOP folder in the shared drive (\\ECT Unit\SOPs\Finalised SOP and WPD) along with Working Practice Documents (WPDs) and relevant ACCORD SOPs. The statistics team also had an ECTU Core SOP Read Receipt form held on the shared drive (see section 3 for the relevant link) and can be used as a guide for what SOPs and WPDs are to be read. QA or delegate will ensure that the new employee is given read only access to this folder and is added to the SOP circulation list.. The new start 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 a training record folder can be arranged. Instructions on creating a staff training record can be found in 'ECTU_SOP_AD_01 Creating and Maintaining a Staff Training Record'.

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- 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 training record, as per SOP.
- 2.2.4 Good Clinical Practice (GCP) training should be undertaken in person through the Edinburgh Clinical Research Facility (ECRF), or online via the NIHR website (see section 3 for links to both websites). It is advised that new starts enrol and complete this training 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. GCP update training must be completed every two years by booking into a GCP refresher course at the ECRF or completing the online update training via the NIHR website (see section 3 for a link to their website). A copy of the GCP certificate should be included in the training record. Each Statistician is responsible for ensuring that their GCP certificate is up to date, although QA may send out a reminder three months before it is due to expire.. Further information can be found in the 'ECTU POL03 Staff Training and Induction Policy'.
- 2.2.5 Information Governance training is recommended for each Statistician due to data access requirements. In particular, the 'Research, General Data Protection Regulation (GDPR) and confidentiality' e-learning modules and quiz should be completed via the Medical Research Council (MRC) learning management system (see section 3). On completion, a copy of the certificate and a screen shot of the module list should be retained for reference.
- 2.2.6 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.
- 2.2.7 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

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- 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 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 and the SAS Install Qualification 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/System validation) in a folder with the user's name. There should be no errors in the output files.
- 2.3.4 An Open Database Connectivity (ODBC) connection should be set up to link to the relevant project(s) within the ECTU database as follows, the ECTU Data Management and Programming Team will provide the project and server name:
- 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.

2.4 Version Control and Naming Conventions

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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

ACCORD website:

www.accord.scot

Edinburgh Clinical Research Facility:

<https://www.ed.ac.uk/clinical-research-facility>

National Institute for Health and Care Research:

<https://www.learn.nihr.ac.uk>

EMA Guidelines:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000602.jsp&mid=WC0b01ac05807d91a4

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>

MRC Learning Management System

<https://byglearning.co.uk/mrcrsc-lms/login/index.php>

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QA inbox details:

qa.ectु@ed.ac.uk

SOP and WPD documents:

[ECTU SOP ST 07 Defining Data Access Requirements for Blinded and Unblinded Statistician](#)

[ECTU SOP AD 01 Creating and Maintaining Staff Training Records v4.0.pdf](#)

[ECTU Central Office POL03: ECTU Staff Induction and Training Policy'](#)

[ECTU Core SOP Read Receipt ST \(QA002d\)](#)

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