ECTU Central Office WPD ECTU_ST_W1: General Guidelines

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**Effective Date:** 31st August 2020

### Authorship and Approval

<table>
<thead>
<tr>
<th>Name and Designation</th>
<th>Author/Reviewer/Approval</th>
<th>Date</th>
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<tbody>
<tr>
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<td>31st August 2020</td>
<td>See retained approval email dated 31st August</td>
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### Document Revision History

<table>
<thead>
<tr>
<th>Version No</th>
<th>Date</th>
<th>Summary of Revisions</th>
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<tr>
<td>1.0</td>
<td>13th March 2017</td>
<td>New document</td>
</tr>
<tr>
<td>2.0</td>
<td>12th March 2018</td>
<td>Changes to SAS Installation Instructions in sections 2.3 and 2.3.1</td>
</tr>
<tr>
<td>3.0</td>
<td>28th August 2020</td>
<td>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.</td>
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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 Arrange access to the ECTU shared drive via 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 Arrange access to the appropriate current project folders, granting unblinded access where necessary. The IT Programmers control access to the unblinded trial data and a request should be made directly to them if access is required. Please refer to ‘ECTU_SOP_ST_07 Defining Data Access Requirements for Blinded and Unblinded Statistician’ for more detail.

2.1.3 Arrange with the quality assurance (QA) Project Co-ordinator for relevant ECTU Standard Operating Practices (SOP) and WPD and a list of the relevant ACCORD SOPs to be sent via email. The QA Project Co-ordinator will also ensure that the new employee is added to the circulation list for future updates.

2.1.4 If the new employee is to run analyses on any CTIMP trials, ensure that they have SAS installed on their computer (see section 2.3 for instructions). Some employees may wish to download additional statistical software, such as R and Stata.

2.2 Training and Guidance

2.2.1 Ensure that the QA Project Co-ordinator is informed of the new employees start date so that a training record check can be arranged. Instructions on creating a staff training record is included in the induction pack or will be sent by the QA Project Co-ordinator. Additional information on creating a training record can be found in ‘ECTU_WPD_AD_W1 Creating and Maintaining a Staff Training Record’.

2.2.2 Each Statistician should add a copy of the certificate from their relevant undergraduate degree, MSc or PhD qualification in statistics in their training record.

2.2.3 Good Clinical Practice (GCP) training should be undertaken every two years through the Edinburgh Clinical Research Facility (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 they will receive a reminder three months before it is due to expire.

2.2.4 Information Governance training is recommended for each Statistician due to data access requirements. In particular, the Research, General Data Protection Regulation (GDPR), confidentially course should be completed. Details of the Medical Research Council (MRC) online course are in section 3.
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 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’).

2.3.2 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 (ECTU Unit/1. ECTU FILING SYSTEM – AMENDED 2010/ECTU Operational/Statistics/System validation) in a folder with the users name. There should be no errors in the output files.

2.3.3 An ODBC connection can be set up to link to the relevant project(s) within the ECTU database as follows:

- 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

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.crts.org.uk/Content.aspx?dbid=crts&layout=CRTS%20Master&theme=CRTS&areaid=118&name=Course&id=3412&type=Content&oid=Screen&uirefid=1272

EMA Guidelines:

ICH Efficacy Guidelines:
https://www.ich.org/page/efficacy-guidelines

IS Connect to University file storage in Windows:
https://www.ed.ac.uk/information-services/computing/desktop-personal/connect-uni-file-storage/windows

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 SAS for Staff and Students
http://www.ed.ac.uk/information-services/computing/desktop-personal/software/main-software-deals/sas/personal-sas

IS Installing Applications
https://www.ed.ac.uk/information-services/computing/desktop-personal/supported/windows7/desktop-features/installing-applications/app-catalog

MRC Learning Management System
https://byglearning.co.uk/mrcrsc-lms/login/index.php

QA Project Co-ordinator contact details:
gqa.ectu@ed.ac.uk (Lynsey Milne)

SOP and WPD documents:
ECTU_SOP_ST_07 Defining Data Access Requirements for Blinded and Unblinded Statistician
ECTU_WPD_AD_W1 Creating and Maintaining a Staff Training Record