ECTU Central Office SOP ECTU_DM_04: Data Entry Procedures

Version No:	1.0
Effective Date:	21 Aug 2020

Authorship and Approval			
Name and Designation	Author/Reviewer/ Approval	Date	Signature
Lynsey Milne, Assistant Data Manager	v1.0 Author	06 Aug 2020	See retained approval email dated 06 Aug 2020
Tony Wackett, Assistant Data Manager	v1.0 Reviewer	06 Aug 2020	See retained approval email dated 06 Aug 2020
Michelle Steven, Data Manager	v1.0 Approval	06 Aug 2020	See retained approval email dated 06 Aug 2020

Document Revision History		
Version No	Date	Summary of Revisions
1.0	21 Aug 2020	Initial creation/New document

1. PURPOSE

This Standard Operating Procedure (SOP) describes the procedures undertaken by ECTU where data entry is completed by ECTU staff from a paper case report form (pCRF) on to the ECTU study database.

2. SCOPE

This SOP applies to all studies where it has been determined that the ECTU Data Management team will provide data entry support for a study, as per ECTU SOP DM 01 Data Management Procedures. This SOP is applicable to members of the ECTU data management or trial management team, where assigned to complete data entry for a study. This SOP also applies to ECTU Trial Managers, where trial management activities have been delegated to ECTU.

3. PROCEDURE

3.1 Data Entry Procedures

3.1.1 Where data entry will be completed by ECTU staff from a pCRF on to an ECTU study database, the Data Management team will provide Data Entry Guidelines using DM005 Data Entry Guidelines Template.

3.1.2 Where the database is provided by an external partner, these guidelines can also be used if the external partner does not provide their own guidance. The Trial Manager is responsible for establishing and documenting if external guidance will supersede the ECTU data management process.

3.1.3 DM005 Data Entry Guidelines Template must be used where pCRF data is entered at ECTU.

3.1.4 The Data Entry Guidelines will include the following:

- Data Entry Information and Responsibilities
  Specify the relevant CRFs that will be entered by ECTU and who will complete this.

- Data Conventions
  DM005 Data Entry Guidelines Template specifies the standard data conventions recommended by the Data Management team.

  Data entry conventions can be applied, where appropriate, to ambiguous or incorrect data that cannot be queried with the source.

  Data conventions may be altered where required on a study-by-study basis (e.g. validated questionnaires may have their own data entry conventions) and additional conventions can be added where necessary.

  Where these will be applied, the CRFs and datapoints to be entered by ECTU personnel will be specified in the guidelines.

- Study Specific Instructions
  Further instructions relating to data entry that may not be covered by the data conventions must be specified in the Data Entry Guidelines template.

3.1.5 The Data Entry Guidelines will be approved by the Trial Manager, Trial Statistician, and the Data Manager/Assistant Data Manager.

3.1.6 Approved Data Entry Guidelines must be in place before data entry begins to establish the basic conventions that will be applied. The guidelines may be further updated, where appropriate, to include specific instructions once the data is being entered on a regular basis.

3.1.7 The approved Data Entry Guidelines will be retained by the Data Management team in the study-specific data management file.

3.2 Document Version Control and Review

3.2.1 All study-specific Data Entry Guidelines and Query and Missing Data Guidelines produced by the Data Management team will be subject to version control and regular reviews. This procedure is detailed in ECTU Central Office SOP ECTU_SOP_DM_07 Data Management Version Control and Document Review

4. RELEVANT DOCUMENTS AND REFERENCES

SOP and WPD:

- ECTU Central Office SOP ECTU_SOP_DM_01 Data Management Procedures
- ECTU Central Office SOP ECTU_SOP_DM_07 Data Management Version Control and Document Review

Available on the ECTU website - www.ed.ac.uk/usher/edinburgh-clinical-trials/supporting-trials/governance/standard-operating-procedures

Templates:

- DM005 Data Entry Guidelines

Available from the Data Management Team – dm.ectu@ed.ac.uk