







ECTU Central Office SOP_DM_04: ECTU Data Entry Identification and Procedures

Version No:	2.0
Issue Date:	11 Jun 2024
Effective Date:	08 Jul 2024

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Document Revision History		
Version No.	Effective Date	Summary of Revisions
1.0	21-Aug-2020	Initial creation
2.0	08 Jul 2024	Updated to new SOP template Responsibilities section added Alterations throughout clarifying responsibilities Title change (previously titled Data Entry Procedures)

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1.0 PURPOSE

This Standard Operating Procedure (SOP) describes the procedures undertaken by ECTU when data is entered by ECTU staff from a paper source onto the study database.

2.0 SCOPE

This SOP applies to all studies where data entry onto the study database will be completed by ECTU staff.

3.0 RESPONSIBILITIES

Where ECTU Data Management staff are delegated the task of data entry, the designated Data Manager, Assistant Data Manager or designee will be responsible for implementing and maintaining Data Entry Guidelines for this purpose. Delegation of this task to the Data Management Team will be established at the start of study as per ECTU Central Office SOP ECTU_DM_01 Data Management Procedures.

The Trial Manager or designee is responsible for reviewing and approving the DM005 Data Entry Guidelines document for the project.

The Trial Statistician or designee is responsible for providing statistical oversight of any data entry conventions applied, and ensuring any data entry conventions required for analysis are included in the Data Entry Guidelines (for example, data entry conventions required for validated questionnaires).

All data entry requirements will be documented in the Data Management Plan (DMP) in section 9 of the TMF of the study specific folder.

4.0 PROCEDURE

4.1 Data Entry Procedures

4.1.1 Data will be entered from paper source onto the database in identical format as much as possible.

4.1.2 If data is presented in an unexpected or non-conformant format which cannot be entered onto the database or may result in an automated query to be triggered, it may be necessary to adopt a data entry convention or instruction to accommodate this. This may include, for example, incorrect date formats or data that is not applicable to the participant.

4.1.3 Data Entry Guidelines for use by ECTU staff will be implemented and maintained using DM005 Data Entry Guidelines template.

4.1.4 The Data Entry Guidelines will include the following:

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

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- **Data Conventions**

DM005 Data Entry Guidelines Template specifies the standard data conventions recommended by the Data Management team. These conventions are commonly applicable to questionnaire data completed by the participant. These may not be applicable to other data types.

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 (for example, validated questionnaires may have their own data entry conventions) and additional conventions can be added where necessary. The Data Management Team can provide advice on additional conventions that may be applied, as required.

- **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.

4.1.5 The Data Entry Guidelines will be reviewed and approved by the Trial Manager or designee, the Data Manager, Assistant Data Manager or designee, and the Trial Statistician or designee. It is important that the Trial Statistician or designee has oversight of any conventions or instructions that will be applied to ensure the data is collected consistently.

4.1.6 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.

4.2 Data Management Document Version Control and Review

4.2.1 All study-specific Data Entry Guidelines 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.

5.0 RELEVANT DOCUMENTS AND REFERENCES

SOP and WPD ([ECTU Website](#)):

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

Templates (on ECTU Shared Drive):

- DM005 Data Entry Guidelines

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Final Audit Report

2024-06-11


Created:	2024-06-10 (British Summer Time)
By:	Tanya Tharakan (tanya.tharakan@ed.ac.uk)
Status:	Signed
Transaction ID:	CBJCHBCAABAAtaMYCcB9eIrWGCQR6UOUF39PmS4aHYbU

"ECTU_SOP_DM_04 ECTU Data Entry Identification and Procedures v2.0" History

-  Document created by Tanya Tharakan (tanya.tharakan@ed.ac.uk)
2024-06-10 - 09:23:12 GMT+1- IP address: 192.41.114.230
-  Document emailed to Lynsey Milne (Lynsey.Milne@ed.ac.uk) for signature
2024-06-10 - 09:26:41 GMT+1
-  Document emailed to Chris Linsley (c.linsley@ed.ac.uk) for signature
2024-06-10 - 09:26:42 GMT+1
-  Document emailed to Kenton D'Mellow (Kenton.D'Mellow@ed.ac.uk) for signature
2024-06-10 - 09:26:42 GMT+1
-  Document emailed to Tanya Tharakan (tanya.tharakan@ed.ac.uk) for signature
2024-06-10 - 09:26:42 GMT+1
-  Email viewed by Lynsey Milne (Lynsey.Milne@ed.ac.uk)
2024-06-10 - 09:29:30 GMT+1- IP address: 104.47.11.62
-  Document e-signed by Lynsey Milne (Lynsey.Milne@ed.ac.uk)
Signature Date: 2024-06-10 - 09:29:36 GMT+1 - Time Source: server- IP address: 192.41.114.230
-  Email viewed by Chris Linsley (c.linsley@ed.ac.uk)
2024-06-10 - 09:31:20 GMT+1- IP address: 104.47.11.254
-  Document e-signed by Chris Linsley (c.linsley@ed.ac.uk)
Signature Date: 2024-06-10 - 09:32:56 GMT+1 - Time Source: server- IP address: 82.35.217.50
-  Email viewed by Kenton D'Mellow (Kenton.D'Mellow@ed.ac.uk)
2024-06-10 - 14:52:54 GMT+1- IP address: 104.47.11.254

 Document e-signed by Kenton D'Mellow (Kenton.D'Mellow@ed.ac.uk)

Signature Date: 2024-06-10 - 14:53:09 GMT+1 - Time Source: server- IP address: 90.243.34.89

 Document e-signed by Tanya Tharakan (tanya.tharakan@ed.ac.uk)

E-signature hosted by Tanya Tharakan (tanya.tharakan@ed.ac.uk)

Signature Date: 2024-06-11 - 13:01:43 GMT+1 - Time Source: server- IP address: 192.41.114.230

 Agreement completed.

2024-06-11 - 13:01:43 GMT+1