## ECTU Central Office SOP ECTU_DM_07: Document Version Control and Review

<table>
<thead>
<tr>
<th>Version No:</th>
<th>1.0</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effective Date:</td>
<td>21 Aug 2020</td>
</tr>
</tbody>
</table>

### Authorship and Approval

<table>
<thead>
<tr>
<th>Name and Designation</th>
<th>Author/Reviewer/Approval</th>
<th>Date</th>
<th>Signature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lynsey Milne, Assistant Data Manager</td>
<td>v1.0 Author</td>
<td>06 Aug 2020</td>
<td>See retained approval email dated 06 Aug 2020</td>
</tr>
<tr>
<td>Tony Wackett, Assistant Data Manager</td>
<td>v1.0 Reviewer</td>
<td>06 Aug 2020</td>
<td>See retained approval email dated 06 Aug 2020</td>
</tr>
<tr>
<td>Michelle Steven, Data Manager</td>
<td>v1.0 Approval</td>
<td>06 Aug 2020</td>
<td>See retained approval email dated 06 Aug 2020</td>
</tr>
</tbody>
</table>

### Document Revision History

<table>
<thead>
<tr>
<th>Version No</th>
<th>Date</th>
<th>Summary of Revisions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.0</td>
<td>21 Aug 2020</td>
<td>Initial creation/New document</td>
</tr>
</tbody>
</table>
1. PURPOSE

This Standard Operating Procedure (SOP) describes the procedure for ensuring all documents produced by the Data Management team are developed and versioned consistently and are reviewed on a regular basis to ensure accuracy and efficacy.

This procedure reflects the requirements specified by ACCORD, who provide study sponsorship for NHS Lothian/University of Edinburgh collaborative studies conducted through ECTU.

2. SCOPE

This SOP applies to all members of the Data Management team who will create, author and maintain documents for both template and study-specific purposes.

3. PROCEDURE

3.1 Development and Management of Data Management Templates

3.1.1 Templates must include the ECTU logo in the header. Where appropriate to the template, the following study-specific information may also be included in the header:

- Study Name/Acronym
- Study Specific Document Name
- Version Number
- Document Date

3.1.2 All templates must include page numbers in the footer in the following format: Page X of X

3.1.3 The template name must be included in the footer of the document. Once finalised, the template name must be in the following format:

Identifier and Document Name TEMPLATE/Version Number/Document Date

3.1.4 If a template is in draft for editing, this must be clear in the footer of the document. Consideration should be given to adding a ‘Draft’ watermark to the document while in draft. Multiple versions of each draft will be tracked using the date.

3.1.5 The template must be named electronically following the same convention as above (e.g. DM001 Data Management Plan TEMPLATE DRAFT V1.0 12Jun2020)

3.1.6 All templates must include a Template Revision History section at the end of the document to record review and a description of updates made following review.

3.1.7 The template identifier is unique to each template, starting with DM001. This identifier will remain the same on all versions of the template. The template identifier will increase in number for each new template, e.g. DM002, DM003)

3.1.8 If a template is withdrawn, the identifier will not be re-used

3.1.9 All templates will be version 1.0 at initial creation. Version numbers will increase by one whole number (e.g. v1.0, v2.0) when a new version of the template is agreed.
3.1.10 Where a template has been specified as part of a Standard Operating Procedure (SOP) and Working Practice Document (WPD), it will be included in the review process for that SOP/WPD as specified in ECTU Central Office SOP ECTU_OP_01 Development and Management of SOP and WPD

3.2 Creating a study-specific document from a Data Management template

The steps below must be followed when creating a study-specific document from a Data Management template:

3.2.1 Do not amend the general format of the template (e.g. the template name in the footer of the document must not be changed). Study specific fields must be completed and the version of the initial study-specific document set to v1.0. Instructions for completing the template are provided on the template or in the related SOP/WPD.

3.2.2 Remove the Template Revision History section from the study-specific document.

3.2.3 The document must be named and saved following the format below:

Study Name and Document Name/Version Number/Date of Study Specific Document

3.2.4 Study-specific documents must follow the version control procedures outlined in 3.1.9 unless otherwise stated in the specific document guidance, SOP or WPD.

3.2.5 Where appropriate, study-specific documentation requires review and approval by other project representatives (e.g. Trial Manager, Chief Investigator). The template or corresponding SOP/WPD will provide further description where formal approval is required.

3.2.6 Document retention requirements will be specified in the applicable SOP/WPD or in the guidance text on the template.

3.3 Reviewing a Study Specific Document

3.3.1 The Data Management team are responsible for reviewing and updating all study-specific documents they have created from a Data Management template. Study-specific documents will be reviewed as part of the DMP review.

4. RELEVANT DOCUMENTS AND REFERENCES

SOP and WPD

ACCORD SOP QA008 Document Version Control

Available on the ACCORD website - www.accord.scot/research-access/resources-researchers/sop

Templates

DM001 Data Management Plan Template
DM005 Data Entry Guidelines Template
DM006 Data Quality Check Control (QC) Plan Template
DM007 Data Quality Control (QC) Check Final Report Template
DM008 Query and Missing Data Guidelines Template

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