MRC Clinical Trials Unit

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DATA MANAGEMENT DOCUMENTATION AND TRAINING SOP

VERSION 1.0

APPROVALS

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All appropriate approvals must have been completed prior to uploading to SOPbox.

UPLOAD TO SOPBOX

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The effective date of this SOP is the day on which it is uploaded to SOPbox and is available to use. This is the date associated with the signature of the SOPbox Administrator.

For the Revision History please see the Version History Summary in SOPbox.

DATA MANAGEMENT DOCUMENTATION AND TRAINING SOP

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The following symbols may be used in this SOP:

Indicates a link to a related document

Indicates instructions to document trial-specific processes elsewhere

Throughout this document the MRC Clinical Trials Unit at UCL, will either be referred to as ‘MRC CTU at UCL’ or ‘the unit’. In instances where neither read well in the sentence, ‘the CTU’ may be used.

1 PURPOSE

The purpose of this SOP is:

- To outline the documents which are needed to facilitate data management in a study
- To outline the procedures related to the training required to conduct data management activities. This includes:
    - Staff working within the unit
    - Site staff providing data either by eDC, rDC or completion of paper CRFs received at the CTU
- To outline the methods which will be used to check that training has been conducted appropriately.

This SOP applies to all CTU studies where the MRC or UCL is the sponsor, or where the sponsor has delegated data handling activities to the CTU, unless it has been agreed with the sponsor that other SOPs will be used.

1.1 DATA MANAGEMENT MODELS

The CTU employs a number of data management models:

1. Use of case report forms (CRFs) which are received by and entered centrally at the CTU. These may be received on paper or electronically, e.g. via secure email. These will be referred to as Paper CRFs throughout the SOP.
2. Electronic data capture (eDC), where sites enter data directly onto the study database into electronic CRFs (eCRFs).
3. Remote data capture (rDC) where data are collected on a paper CRF and then entered on to the study database at a location offsite (i.e. not at the CTU).

Some studies may use a mixture of these models.

2 RESPONSIBILITY AND ROLES

The following table lists the roles relevant to this SOP and a brief description of their responsibilities.

This SOP will be circulated to be Read and Understood to all appropriate roles identified in the training matrix.

ROLE	RESPONSIBILITIES
Trial Management Team	• Ensure all data management activities are documented appropriately • Review the DMP and any associated documents at least annually or following changes to the study • Develop study specific training materials for site staff prior to the first participant being recruited • Deliver study specific data management training to new study team members joining the MRC CTU at UCL
Clinical Project Manager	• Ensure the first version of the Data Management Plan is in place before the first participant is recruited • Notify the Data Scientist Team that there are new staff with data management responsibilities in their teams • Ensure data entry checking is completed for new study staff with data entry responsibility
Data Manager	• Write and make necessary updates to the DMP and any associated documents • Conduct the data entry checking process for new study team members/site staff who are responsible for entering data into the study database • Ensure study data management training materials are updated appropriately following protocol/CRF/database changes • Deliver the study specific data management training to site staff as necessary
Statistician	• Input into and review the DMP and relevant associated documents
Data Scientists	• Deliver data management training on MRC CTU at UCL procedures to internal staff • Provide templates for studies to check data entry of new study team members • Provide certificates of successful completion of data entry checking for new study team members • Oversight of the data entry checking for new staff process • Provide support to study teams to train new team members as required
Data Management Systems	• Provide generic system training materials

3 PROCEDURES

3.1 DOCUMENTATION OF DATA MANAGEMENT PROCEDURES

All procedures relating to the data management of a study at the CTU should be documented.

All studies should have a Data Management Plan (DMP). Some detailed procedures may be found in associated documents e.g. data entry guidelines and CRF Completion Guidelines, but these are still considered to be part of the overall study data management documentation.

The DMP template outlines the general expected content of a DMP and has extensive guidance on completing the document.

The study team are responsible for maintaining all data management documentation and ensuring that it is reviewed at least annually, and updated if changes are needed. Whenever changes are made to the study risk assessment, the study team should consider whether there are any associated changes required to the data management documentation.

Studies should have their first version of the DMP signed off prior to opening to recruitment. Data management procedures should be documented in a finalised version of the DMP or associated document before those procedures are undertaken in the study.

3.2 GENERAL DATA MANAGEMENT TRAINING FOR INTERNAL STAFF

There are two general data management training sessions which are developed and delivered by the Data Scientists at the CTU. These sessions cover the appropriate legislation, including the most relevant principles of Good Clinical Practice (GCP) and in depth training on the principles of the Data Management related SOPs. These are:

- Basic Principles of Data Management – this is aimed specifically at Trials Assistants
- Advanced Principles of Data Management - this is aimed specifically at:
    - Data Managers
    - Trial Managers who are new to the unit

All new Trial Assistants and Data Managers should attend one of these sessions within a month of beginning in post, where possible. Trial Managers should attend the next available session. Certificates will be issued following completion of this training and should be placed in the individuals training file.

The Advanced Principles of Data Management session is also open to Statisticians who are new to the unit and feel it may be useful.

3.3 STUDY SPECIFIC TRAINING

All procedures relating to study specific training should be detailed in the Data Management Plan (DMP).

For more information on what data management training should be provided at site initiation see the Site Evaluation and Training SOP.

3.3.1 WHO IS RESPONSIBLE FOR PROVIDING TRAINING MATERIALS

Data Management Systems will provide system specific training materials, such as the CACTUS User Guide.

The Study team are responsible for developing any study specific training material and associated training processes, prior to the first participant being recruited, as detailed in the following sections.

3.3.2 NEW DATA MANAGER TRAINING PROCESS

New study staff with data management responsibilities, which includes people moving between studies, should receive study specific training in order to fulfil the requirements of their role. This would be delivered by members of the study team. The DMP should be used as part of the training process for new study team members with data management responsibility.

For more information see the Data Manager Handover WI, Data Manager Handover notes template and Data Manager Handover Schedule.

The WI and associated templates referenced above provide a framework for the delivery of study specific training. The completed Handover Schedule could then be placed in the individuals training file to evidence this training.

3.3.3 TRAINING REQUIRED WHEN INTERNAL STAFF ARE ENTERING DATA ON THE STUDY DATABASE

3.3.3.A TRAINING MATERIALS REQUIRED:

- Database training materials. These may be a separate document or incorporated into the data entry guidelines.
- Data entry guidelines (or equivalent).

3.3.3.B TRAINING PROCESS

Any study team member who requires access to the study database, which would allow them to enter or edit data, must undergo a data entry checking process before they are allowed to freely enter data onto the database. The checking process is required for each trial database they will be using.

This applies to:

- Any new member of staff requiring access to enter data on a study database
- Any study team member who has no access or read/view-only access but subsequently requires access to enter or edit data.

- An existing member of staff who will be entering a wider range of CRFs than previously checked.
- An existing members of staff who will be entering data on a different trial database than previously checked either permanently or temporarily

The spreadsheet which documents the checking process will be kept by the Data Scientists and a certificate issued once the checking process has been passed. This should be placed in the individuals training file.

Full details of this process can be found in the Data Entry Checking for New Users of a Study Database WI.

Anyone requiring access to a study database, who has not completed this process should only be granted read-view only access.

Two situations where data entry checking might not be required are:

- For a new study where the staff member has been involved in the CRF and database development process including the testing of the database
- Where the study is using double data entry, although the study team may choose to still perform some checking in order to monitor any training issues, such as incorrectly raising manual queries. If this is the case it should be documented in the Data Management Plan (DMP).

3.3.4 TRAINING REQUIRED WHEN SITE STAFF ARE COMPLETING PAPER CRFS

3.3.4.A TRAINING MATERIALS REQUIRED:

- CRF Completion Guidelines (or equivalent). This should include:
    - general completion guidelines e.g. date formats
    - instructions on how to make changes to CRFs in line with GCP requirements
    - query resolution process e.g. how they will be notified and how they are expected to provide the resolutions.

See SOPbox for CRF Completion Guidelines Template.

For studies which use paper CRFs, but where site staff randomise participants through a system, information on this process may be included in the CRF Completion Guidelines or in a separate guidance document.

3.3.4.B TRAINING PROCESS:

Once the study team is notified that a new member of staff at site will be undertaking CRF completion, the study team must check the person has been added to the Signature List and Delegation of Responsibility Log with the appropriate roles/tasks delegated before training commences. The new site staff should at a minimum be given the CRF Completion Guidelines document and study teams may wish to provide further training as necessary.

3.3.5 TRAINING REQUIRED WHEN EXTERNAL STAFF ARE ENTERING DATA ON TO THE STUDY DATABASE

3.3.5.A TRAINING MATERIALS REQUIRED:

- Study database system training materials, this could be in the form of a word document, a presentation or a video, as appropriate to the study.
- Dummy CRFs for data entry checking. These should:
    - cover scenarios that will adequately indicate whether they have understood the database and study-specific training.
    - cover various participant scenarios that may occur
    - include scenarios covering any query resolution processes that the sites will have to follow, to ensure that they understand these processes fully
    - should not include real patient data
    - should have clinical input to ensure the data is feasible and realistic
- Data entry guidelines – these could include frequently asked questions if helpful

3.3.5.B TRAINING PROCESS:

Once the study team is notified that a new member of staff at site requires training on the study database, the study team must ensure the person has been added to the Signature List and Delegation of Responsibility Log with the appropriate roles/tasks delegated.

Site staff that will be undertaking data entry directly on to the study database in both eDC and rDC studies must have received database training, preferably by CTU staff. This training should consist of both generic system and study specific training.

Once this initial training is complete, they must then enter the dummy CRFs which have been prepared by the study team. It is recommended that site staff are granted access to a training database if available to enter these dummy CRFs, but it may also be done on the test database.

Study team members at the CTU should complete the checking of this data entry/query resolution. All training issues or errors must be resolved before site staff will be granted access to the live database. Successful completion of this training should be documented.

Please note: this process is recommended even for sites using double data entry to ensure that they fully understand the study database and querying processes, although the volume of dummy data required to be entered may be significantly less for these sites than for those using single data entry.

It should be made clear to site staff that the sharing of passwords or allowing someone else to enter data under their username is strictly prohibited. Where site staff are required to enter a password every time they access the system, each member of site staff should sign a Non Disclosure of Password Agreement before being allowed to begin data entry on the live database.

See SOPbox for Non Disclosure of Password Agreement template

3.4 UPDATES TO STUDY CRFS AND DATABASE AFTER RECRUITMENT STARTS

When there are changes to the study CRFs and/or database the study team should update the training documents as necessary. This should be started as early in the process of making changes as possible, to ensure enough time is available to make the relevant updates.

See the CRF Development and Maintenance SOP for information on making changes to CRFs.

When changes are made to the study CRFs and/or database the DMP and associated working practices should be reviewed to ensure any changes to procedures are updated.

There should also be a discussion to assess the scope and impact of the changes and whether the study teams feel other methods of training are required e.g. teleconferences or face to face training.

4 RELATED DOCUMENTS

For further information on this topic, see also:

- CRF Development and Maintenance SOP
- Data Entry Checking for New Users of a Study Database WI
- Data Manager Handover WI
- Data Management Plan Template