MRC Clinical Trials Unit

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DATA RECEIPT AND ENTRY 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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Nancy Tappenden	SOPbox Administrator	Nancy Tappenden Digitally signed by Nancy Tappenden Date: 2019.09.05 20:12:40 +01'00'	06-Sep-2019

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 RECEIPT AND ENTRY 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 procedures related to the receipt and entry of study data

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 an escalation policy is in place to deal with any issues relating to eligibility and safety • Create a list of manual checks to be completed at data receipt • Compile a list of Self Evident Corrections (SECs) if appropriate and where SECs are used ensure the Principal Investigator at each site has signed off the list before use • Define any data coding which is to be done and ensure all coding is reviewed and done consistently throughout the life of the study • Ensure there is a process in place for documenting receipt and checking of any electronic data received outside of the database e.g. lab data
Data Manager/Trial Assistant	• Ensure CRFs/eCRFs are completed by site staff appropriately • Document/track receipt of data • Complete data entry in line with unit and study guidance • Perform manual checks as required at data receipt
Data Scientist	• Provide oversight and guidance on these processes as appropriate for the study

3 PROCEDURES

All study specific procedures relating to data receipt and entry should be detailed in the Data Management Plan (DMP).

3.1 MANAGING DATA RECEIPT

3.1.1 PAPER CRFS

The following processes apply to any CRF which is received at the unit. If the study is rDC or eDC and receives a CRF for handling or entry at the CTU, these processes should also be followed and documented in the Data Management Plan.

3.1.1.A MONITORING PAPER CRF COMPLETION

Each study should have a specific list of manual checks to be performed on the CRFs by a study team member upon receipt and/or prior to data entry, these may include:

- Data that may indicate a safety issue for the participant
- Data that may indicate ineligibility of the participant
- Ensuring that the CRF Completion Guidelines (or equivalent guidance documents) and GCP principles of CRF completion are being followed by the site. If sites are not adhering to the study specific principles of CRF Completion provided to them, then consideration must be given to whether the site requires further training.

Studies should have an escalation policy in place to deal with these situations should they arise. It should detail:

- what requires escalation
- who the issue should be escalated to
- a time scale for escalation
- any subsequent documentation that is required e.g. adding the issue to a tracker

See Data Cleaning and Quality SOP for more information on checking safety and eligibility data

3.1.1.B MANAGING PAPER CRFS WHICH CANNOT BE ENTERED

There may be several reasons why a paper CRF cannot be entered onto the database immediately, including (but not limited to) the following:

- The CRF has not been signed by someone that has been delegated to do so on the site delegation log
- An acceptable version of the CRF has not been completed
- Date of completion on the CRF is prior to the assessment/visit date

In these situations, the site must be notified in line with study procedures and asked to provide an updated CRF completed correctly. Depending on the size and nature of the study, the original CRF can then either be:

- Stored in a specific location for CRFs that cannot currently be entered, or
- Marked clearly as 'not entered' and filed in the participant file, ensuring it is also logged somewhere (e.g. database query or tracking log) that it has been received, but has issues preventing data entry. This can then be chased up in the future if needed.

When the updated CRF is received and the issue has been resolved, it can then be entered on to the database. Both the original CRF and the updated CRF should be filed in the patient folder, with the original marked as 'not entered' and ideally attached to the updated version.

3.1.1.C DOCUMENTING PAPER CRF RECEIPT

CRFs should be dated upon receipt in some way to record when they were received at the CTU. Examples of how this can be done are:

- Having a space at the bottom of each CRF page for adding the date of receipt
- Stamp/writing the date on the back of the CRF making clear that it is the received date.
- Some studies receive CRFs via fax or efax, in which case the date received will already be present on the CRF.

If studies receive CRFs via email, they should be printed and the date of receipt added using one of the examples above.

Where a study has the ability to log receipt of CRFs in their study database, this should ideally be done on the day of receipt.

3.1.1.D RECEIPT OF UPDATED CRFS

Whenever an updated copy of a previously entered CRF is requested from site for any reason, the updated data should be entered and then ideally attached to the original when filed ; the original should be clearly marked as 'superseded', but should never be destroyed.

3.1.2 ELECTRONIC DATA

3.1.2.A ECRF DATA

Where data is entered directly on to the study database by staff external to the CTU, the date of entry will be captured in the database audit trail.

3.1.2.B OTHER ELECTRONIC DATA

If other types of electronic data are planned to be received for a study outside of the database, such as lab data or data extracts, then there should be a process developed by the study team to log receipt of this data at the CTU and to document checks have been performed. It should be ensured that data of this nature is being sent securely.

Please see the Management of Personal Data SOP for more information on sending data securely

3.2 DATA ENTRY

Data entry should only be performed by those who have undergone the appropriate training.

Please see the Data Management Documentation and Training SOP for more information

Data should be entered as it appears on the paper CRF, so that it corresponds with the copy retained by investigator sites.

Data which is unclear should be queried with the site; presumptions should not be made as to the intended data values.

Studies should have a set of data entry guidelines to ensure consistency.

3.2.1 SELF EVIDENT CORRECTIONS (SECS)

There may be instances where self evident corrections (SECs) are permissible at data entry. SECs are changes that can be made to the data by the study team when entering CRFs onto the database without querying this change with the site. The paper CRF should not be amended by the study team during this process. For eDC studies, these changes can be made to the database by the study team when they are reviewing the data entered by sites.

If a study is planning to use SECs, they must first draft a proposed list of the situations in which these corrections can be made. The list of SECs should only cover situations where there is no doubt over the meaning of the data that the site provided on the CRF, and each SEC must be written in a way that very specifically explains the allowed correction.

For example, if a CRF is received with information about concomitant medications taken by a patient listed by the site, but the preceding question 'Is the patient taking any concomitant medications?' has not been answered, then an acceptable SEC would be to allow the data enterer to answer that question on the database as 'Yes' without querying by the site. However, if there was information given about concomitant medications but the question 'Is the patient taking any concomitant medications?' had actually been answered 'No', there is a clear discrepancy between these pieces of data and this should be queried with site rather than corrected using an SEC.

Once a list of SECs have been drafted for a study, they must be approved by the Principal Investigator (PI) at each site before they are finalised and implemented. This list should be versioned, and if any changes or additions are made later, then these updates must again be signed off by PIs at all sites before being implemented.

If there is ever uncertainty about whether to use a self evident correction, a database query should always be raised and the data should not be corrected until a response is received from site providing clarification.

For a list of common SEC examples and a template for getting these signed off by sites, see the 'SEC Examples and PI Sign-Off Template'

Studies that choose to implement a self evident corrections policy should reference the current version of the SEC document in the data entry guidelines/DMP to ensure that this policy is being followed by data entry staff.

3.2.2 DATA CORRECTIONS

An audit trail must be maintained for all data, which means that any changes and/or corrections by sites to data on a paper CRF should be:

- Dated and initialled by the person making the change
- The incorrect data should be crossed through so as not to obscure it, and the correction provided along with an explanation if necessary

If a paper CRF has been amended by site staff, but the correction has not been initialled and dated as per GCP guidelines, this piece of data should not be entered but a query should be added to the database where possible. An updated CRF with the initials and date assigned to the correction should be requested. When the updated form arrives, it will ideally be attached to the original form in the patient files.

3.2.3 AFTER DATA ENTRY

Data entry should be confirmed in some way on the paper CRF. Examples of how this may be done are:

- Having a space at the bottom of each CRF page for the date of entry and initials of the enterer to be written, or
- The date and initials can be stamped/written on the back of the CRF, making clear that it is the date of entry.

3.2.4 DATA CODING

There are several different methods of data coding that can be used on a study. These include:

- Category options ticked on a CRF and when entered, the database automatically assigns code as defined in the metadata e.g. No may be saved as code ‘0’ and Yes, would be saved as ‘1’
- Sites select a code from a pre-defined list or dictionary and enter the code onto the CRF (usually without the text) e.g. drug coding lists.
- Sites enter free text onto CRF and staff at CTU code this using the appropriate coding list or dictionary e.g. ‘Specify Other Toxicity’ questions

Data coding should be done consistently throughout the life of the study i.e. database codes assigned to categories should remain the same. New categories or changes to categories should be represented by new database codes.

Where common coding dictionaries such as MedDRA or CTCAE are used, management of version changes in those dictionaries, should be considered and included in the DMP.

If the coding is being done manually at the CTU, the process should be described clearly in the Data Management Plan or Safety Management Plan as appropriate. Anyone conducting manual coding should be trained in the process and documented in their training file. It is recommended that any manual coding and any updates to coding are reviewed and verified by the trial physician or appropriate alternative.

Any coding done by site staff should be detailed in site training documents.

3.3 STORAGE OF PAPER CRFS

Paper CRFs should always be kept in a secure area when not in use, and stored in such a way that unentered CRFs cannot become mixed up with those awaiting filing after data entry.

4 RELATED DOCUMENTS

For further information on this topic, see also:

- Data Cleaning and Quality SOP
- Management of Participant Personal Data SOP
- Data Management Documentation and Training SOP