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CRF AND WORKSHEET DEVELOPMENT AND MAINTENANCE SOP

VERSION 2.0

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

CRF AND WORKSHEET DEVELOPMENT AND MAINTENANCE 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 for developing and maintaining CRFs to facilitate optimal data collection and quality
- To ensure the CRFs are designed to collect data to meet the requirements of the study protocol
- To outline procedures for the ongoing maintenance of CRFs once the study has opened
- To define the MRC CTU at UCL roles and responsibilities involved in developing and maintaining CRFs.

For reference, Good Clinical Practice ICH E6 (R2) defines a Case Report Form (CRF) as 'a printed, optical, or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial subject.'

For the purpose of this SOP:

- 'paper CRF' will refer to the paper version of a CRF
- 'eCRF' refers to the electronic version of a CRF in a database
- 'CRF' will be used as a blanket term when referring to both above types of forms
- 'worksheet(s)' (sometimes known as "Source data worksheets") refers to a paper document used to facilitate collection of source data for the participant notes/records at site, where the primary data collection method for the study is electronic data capture (eDC). The worksheet may directly collect source data, especially in cases where data is not routinely collected, and/or act as a clear indicator of what data must be recorded in the participant notes/records. Each worksheet must be designed to collect all of the data needed for the relevant eCRF(s).

This SOP applies to all studies where the UCL is the sponsor, or where the sponsor has delegated CRF design activities to the unit, unless it has been agreed with the sponsor that other SOPs will be used. This SOP may be used as a reference to review CRFs and worksheets, which are developed externally on behalf of the MRC CTU at UCL.

If data from a study may be used to support a licensing application or extension, data may need to be provided in a way that is aligned to CDISC standards. This must be discussed fully with your DMS team members to explore the fields that might need to be included in the CRFs. However, this SOP will not provide any specific guidance on working with CDISC.

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 Group (TMG) including clinical input	• Complete and approve the Protocol Data Collection Assessment spreadsheet, ensuring all protocol requirements are addressed • Alongside DMS, design, develop and maintain the CRFs based on the needs of the study protocol, including the list of CRFs and the schedule • Ensure paper CRFs/worksheets are appropriately version controlled throughout the study • Continual review of CRFs/worksheets to ensure they are fit for purpose • Create and maintain guidelines for CRF completion for site staff • Ensure any relevant specialists or patient representatives are consulted as appropriate (see table in section 3.1 for more information) • Ensure appropriate approval of CRFs from all relevant parties (as agreed by TMT for each release)
Data Management Systems Project Manager/Data Scientist	• Review the protocol, recording data collection requirements in the Protocol Data Collection Assessment • Ensure database requirements are taken into account when designing and developing CRFs • Alongside the TMG, design, develop and maintain the CRFs • Consult with CDISC specialist group where required, to define CRF questions and devise final wording • Review CRFs and worksheets to ensure they are fit for purpose
Statistician (in addition to responsibilities as a member of the TMG)	• Ensure the data collected on the CRFs are sufficient to answer the research questions in the study protocol and in line with the Statistical Analysis Plan (SAP)

3 PROCEDURES

Quality assurance is one of the main principles of Good Clinical Practice (GCP), so any methods of data capture must be designed to ensure the collection of high quality data. Studies which utilise CRFs must therefore ensure those CRFs are clear, well presented and unambiguous for those completing them and only collect data that is required by the protocol. This is intended to help reduce the amount of missing data and data queries, which can arise due to poor design.

The purpose of CRFs is to collect the data specified to meet the needs of the study protocol. It is therefore very important to ensure that adequate time and resource are assigned to developing the CRFs.

CRF design is expected to begin after the initial draft of the protocol data collection assessment spreadsheet has been completed.

3.1 CRF DEVELOPMENT – WHO SHOULD INPUT?

When CRFs are being designed and updated, the following factors must be taken into consideration. These will require input from across the trial management team and specifically require input from those in the table below:

Considerations	Input from
Does the data being collected make sense for the study population?	Clinicians or other medical expertise
Is the data being collected in such a way that it can be analysed appropriately?	Statistician
Is the data being collected in such a way that it can be stored on the database?	Data Scientist and/or Database System Programmer
Is the data being collected in such a way that it is suitable to the data management model, i.e. paper versus electronic CRFs, data entry at the MRC CTU versus data entered remotely either by sites or co-ordinating data centres?	Data Scientist and/or Database System Programmer Data Managers and/or Trial Manager
Is the data being collected in such a way to support effective study management?	Trial Manager
Is the data being collected needed to ensure the safety of the patient and to assess the outcomes of the trial?	All roles within the study team
Is the data being collected in such a way to promote good data quality?	
Are the CRFs patient facing? Note that validated instruments/sections, such as EQ-5D, may not be allowed to be edited but the overall design and instructions may be influenced	Patient and Participant Involvement representatives

It is also important to keep usability of the CRFs in mind, so asking a clinical representative of the Trial Management Group and/or users at site to complete some drafts CRFs and provide feedback is highly recommended.

The development process is generally iterative, a draft CRF is produced, which is then reviewed by the study team with the factors listed above in mind. Feedback must be provided and discussed by

the group and incorporated as appropriate. This next draft will then be reviewed and so on. See section 3.12 for information on how to version control CRFs.

3.1.1 WORKSHEETS IN ELECTRONIC DATA CAPTURE (EDC) STUDIES

In eDC studies, a set of worksheets must be maintained as a faithful representation of the eCRFs. A single worksheet may contain multiple eCRFs e.g. all eCRFs at a visit in a single worksheet. Sites are expected to complete the worksheets to record the source data to form part of the participant notes unless the data is captured elsewhere e.g. lab report printouts.

3.2 DEFINING THE LIST OF CRFS REQUIRED FOR THE STUDY

When defining the CRFs that will be required for the study, consider:

1. When the data will be available
2. Where it will be collected
3. Who will be completing the CRF
4. Whether an appropriate signatory for the CRF will be available

See the Defining CRFs and CRF Questions Working Instruction

3.3 COLLECTING DATA TO MEET THE NEEDS OF THE PROTOCOL

When deciding what data to collect on CRFs, it is important to remember that there is a balance to be found between the study's need for data and the impact of that data collection on the site staff, the participants, the database, and the study management team.

The General Data Protection Regulation states that data shall only be collected that is 'adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed' i.e. data which are required to meet the needs of the protocol. This will generally consist of the following:

- For analysis of primary or secondary outcome measures as stated in the study protocol e.g. date of death, where survival is a primary outcome measure
- To ensure participant eligibility e.g. viral load at screening
- To ensure participants' safety e.g. collecting blood pressure at every follow up to monitor hypertension, if this might result in discontinuation of study treatment
- To facilitate study management e.g. asking if the diary card has been returned by the participant at each follow up visit

It is advisable to review the content of all CRFs/Worksheets against the principles defined in the Defining CRFs and CRF Questions WI before database testing begins.

See the Defining CRFs and CRF Questions Working Instruction

When duplicating questions across forms, e.g. for SAE reconciliation, ensure that this is necessary.

3.3.1 Collecting Data in International Studies

In International studies, consideration ought to be made for different data collection formats e.g. date formats, as well as potential language barriers. All data entered into the database must be in English, but the trial management team can consider whether paper CRFs/worksheets need to be translated for local use. There must be a process in place to document translation by an appropriate individual.

3.3.2 Completing the Protocol Data Collection Assessment spreadsheet

To document that all data outlined in the protocol are being collected and checked appropriately, new studies or studies undergoing protocol changes must complete the Protocol Data Collection Assessment spreadsheet. Completion of the template must be discussed with your Data Scientist.

See the Protocol Data Collection Assessment spreadsheet template in SOPbox

The spreadsheet will be completed by the trial team, ensuring input from a Data Scientist, Statistician and Clinician. If it is decided that any data-related requirement from the protocol will not be collected on a CRF or checked by a planned process, then the reason for this must be documented in the spreadsheet along with the trial team member making this decision.

Please note the following regarding eligibility related data collection or checks:

- If there is data available to confirm an eligibility criterion then it must be collected and checked before the participant is enrolled onto the study. For example, if a laboratory assay has to be above or below a certain value for the participant to be eligible, then the value must be collected and checked prior to enrolment. If an eligibility criteria has no direct value that can be checked associated with it, for example whether the participant has had a previous severe reaction to a particular drug, which may only be able to be captured as a Yes/No response that must still be collected and checked prior to enrolment.
- If it is not feasible for the database system to check the data prior to enrolment, then confirmation of eligibility must be documented with the trial team prior to enrolment. An example process may be that the site faxes a copy of the completed randomisation checklist, signed off by a clinician at site prior to enrolment, to the trial team who send a confirmation of eligibility back to the site staff.

Please note the following regarding safety-related data collection or checks

- If data is received that flags up a safety related concern for the participant, such as specific toxicities which would necessitate stopping trial treatment immediately or would indicate a Serious Adverse Event which must be reported, then the assessment must be collected and checked within 1 working day of receipt at the Unit. Missing safety assessments must be flagged immediately on receipt and chased at site in an expedited fashion. Checks on these assessments must be programmed to be checked prior to enrolment. The process must also be added to the study Risk Assessment documentation.

A first draft of the Protocol Data Collection Assessment spreadsheet must be completed before CRF development has begun, and there must be an approved version of the spreadsheet in place before the final CRFs/worksheets are released to any sites. The approvers for this document must include the statistician, a trial clinician and the clinical project manager or delegate (delegation must be documented e.g. in meeting minutes or via email).

3.4 CRF/WORKSHEET DESIGN SOFTWARE

Microsoft Publisher is the preferred package for developing CRFs and worksheets. For examples of good CRF or worksheet design, please contact the Data Scientist team.

See the CRF Template/s and CRF Question Kit in SOPbox

3.5 PAPER CRF/WORKSHEET DESIGN – FORM IDENTIFIERS

It is recommended that all paper CRFs or worksheets be given both a name and a unique identifier such as a number (e.g. Form01 – Screening). This helps in identifying the paper CRFs/worksheets both at site, and internally. Numbers are particularly useful if sites are required to complete paper CRFs/worksheets in a particular sequence.

3.6 PAPER CRF/WORKSHEET DESIGN – HEADER AND FOOTER FIELDS

When paper CRFs/worksheets are being designed, the study team must consider which header items are required for the database system in use, and which are most appropriate for each form. It is important to discuss this with the DMS Development Team to ensure the header fields required for your database system are collected i.e. each database system (CACTUS, MACRO, OpenClinica) requires different header fields which must be collected.

For worksheets, consider whether any footer is needed during the initial development.

The table below describes items, which are expected to appear in the header or footer of forms, split by the type of form and with additional explanation given where needed. The placement of questions in the header or footer of forms must be consistent across forms in a relative fashion e.g. from left to right in the order Trial number, Date of Birth, Date of Visit.

Data items	Paper CRF	Worksheet	eCRF
CRF identifier and/or name e.g. Form01 – Screening Form	Yes	Yes	Yes
Page numbers e.g. Page 1 of 3	Yes	Yes	If applicable
Study Number/Trial ID	Yes	Yes	Yes
At least one indirect patient identifier used to check the form has been completed for the correct patient e.g. • Date of Birth/Partial Date of Birth • Initials	Yes	Yes	Yes
Visit identifier where appropriate e.g. Week 1, Week 2 etc.	Yes	Yes	Yes

A date that can be used to identify the Form i.e. Form Date (where appropriate, this may be in the header or as another question placed early on the form) • Visit Date • Date Log Started • Screening Date	Yes	Yes	Depends on the requirements of the database system used
Version number and date (Note that Version numbers do not always match protocol version numbers)	Yes	Yes	No
Details of the person verifying the data on the form	Yes – ideally full name, Signature, Date, including a statement to verify this is a certified copy of the source data.	Yes – It must be clear who has captured the source data e.g. initials or signature. There must be a date present on the worksheet to denote when the data was collected	Yes - electronic signature equivalent via the capabilities of the system you are using
Date of receipt at the CTU/Coordinating Data Centre	Recommended	No	The date the data was entered must be captured in the audit trail
Date of entry at the CTU/Coordinating Data Centre	Recommended	No	The date the data was entered must be captured in the audit trail
Initials of person completing data entry	Recommended – must be recorded somewhere on the form as per Data Entry and Receipt SOP	No	The username of the person entering the data must be captured in the audit trail

For more information on collection of participant identifiers, see the Management of Personal Data SOP.

See the CRF Template/s in SOPBOX for the standard unit header and further guidance.

Please refer to the Data Receipt and Entry SOP (SOP_090) in SOPBOX for guidance on how to record CRF receipt and recording data entry

Ideally, the full CRF header will be used on all CRF or worksheet pages. However, it is recognised that in some instances studies may wish to use an abridged version on any pages after the first one. At a minimum, this is expected to include:

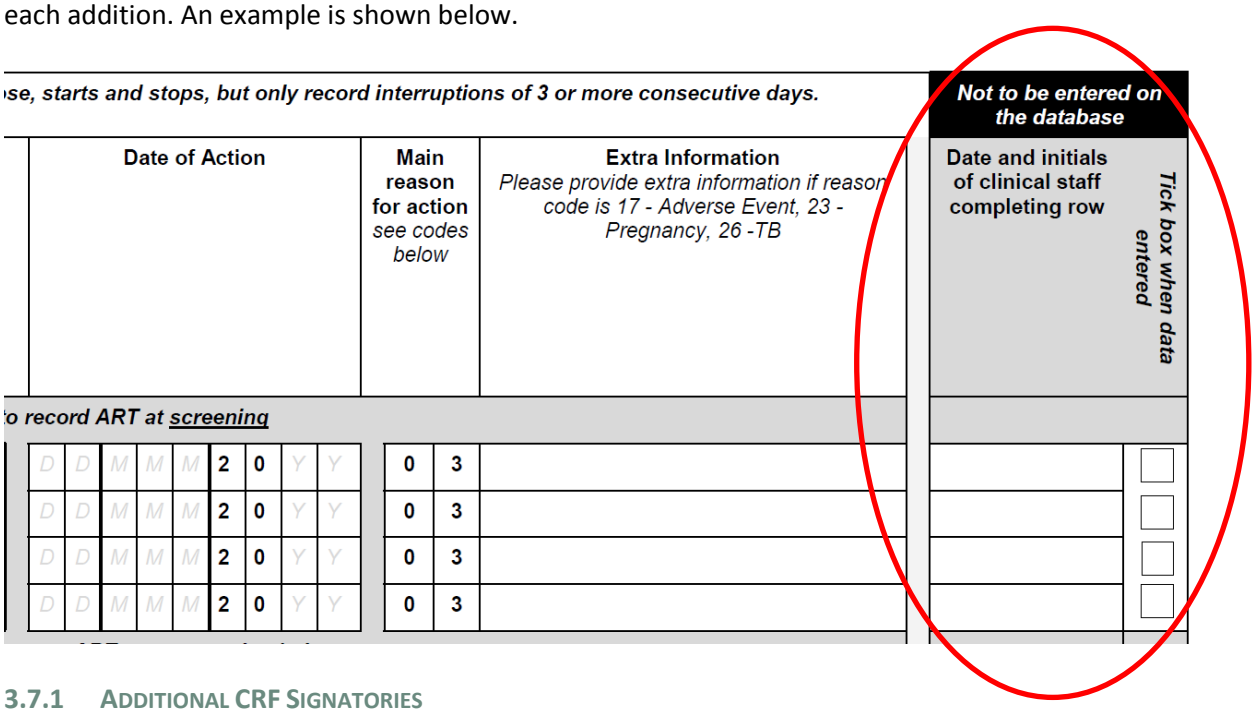
- Study Number
- One other indirect identifier
- Visit identifier where appropriate

3.6.1 UNIQUE ID

Every study participant must have a unique ID, often referred to as Study Number or Trial Number. The unique ID must remain the same throughout the study, from initial data collection (e.g. screening) although it may have additional letters or numbers appended to indicate that a further action has occurred, such as the participant moving from registration to randomisation.

3.7 SIGNING OFF LOG STYLE FORM DATA

If data collected on one CRF may be entered in multiple instances or by multiple members of staff (e.g. Concomitant Medications CRF in a log format), a space for sign-off and date must be present for each addition. An example is shown below.



se, starts and stops, but only record interruptions of 3 or more consecutive days.

Date of Action	Main reason for action *see codes below*	Extra Information *Please provide extra information if reason code is 17 - Adverse Event, 23 - Pregnancy, 26 -TB*	Not to be entered on the database: Date and initials of clinical staff completing row	Not to be entered on the database: Tick box when data entered
o record ART at screening				
D D M M M 2 0 Y Y	0 3			☐
D D M M M 2 0 Y Y	0 3			☐
D D M M M 2 0 Y Y	0 3			☐
D D M M M 2 0 Y Y	0 3			☐

3.7.1 ADDITIONAL CRF SIGNATORIES

Some CRF data may require input from a specified role in addition to the member of staff completing the CRF. For example, participant eligibility, serious adverse event medical review or cause of death may require a clinical assessment. To verify this, studies may choose to capture an additional name, signature and date of signature and possibly role for this member of staff on the CRF collecting these data.

3.8 COLLECTING SAFETY DATA

There is a standard SAE CRF template, which has been created for the Unit and must be used by each study. There are also a set of guidelines on how it can be adapted based on study characteristics. The MRC CTU at UCL Safety Group must review all new or updated SAE CRFs/worksheets prior to their use in the trial to ensure all questions collecting data for safety management are present. Any revisions to the standard SAE form must be documented on the PV checklist.

See the standard SAE CRF Template and associated guidelines in SOPbox

If a study has exempted any SAEs from expedited reporting, these will still need to be identifiable from the study database for inclusion in reviews and the cumulative table of the Development Safety Update Report (DSUR). Study CRFs must collect appropriate data to allow exempted events to be detected, e.g. if the event is serious.

3.9 PILOTING OF CRF AND WORKSHEETS

Once a good draft of a paper CRF or worksheet has been developed, piloting with a clinical representative of the Trial Management Group and/or at site is highly recommended to assess whether they can be completed as intended in the clinical setting, and that the questions flow, make sense and are formatted correctly. Ideally, a clinical representative will fill out a few sets of forms with data that is realistic for the participants in the study from a number of participant case studies. These scenarios must include complex cases to assess how easily data can be captured under the range of circumstances expected in the study. These completed forms may also be useful for testing the study database when it is developed and when it comes to developing training materials for site staff to know which forms are due in each scenario.

3.10 FINALISATION OF CRFS/WORKSHEETS

When the study team have a draft CRF that they feel is ready to become the new/next version of the CRF, they must ensure that all appropriate members of the study team are satisfied with the content and layout, bearing in mind its impact on study management, clinical setting, database, analyses, and any other relevant factors.

As part of the finalisation process, paper CRFs and worksheets must be reviewed to check for formatting and layout consistency, both within and across CRFs/worksheets, using the Paper CRF/Worksheet Finalisation Checklists. This review must be documented in the TMF.

See the Paper CRF Finalisation Checklist & Worksheet Finalisation Checklist in SOPbox.

3.11 APPROVAL OF CRFS

For a new CRF, approval is expected to include clinical, statistical, and DMS representatives as well the trial team member completing the paper CRF/Worksheet finalisation checklist.

For any updates to CRFs, the relevant team members needed to approve must be defined by the TMT, with this list of approver documented e.g. in meeting minutes or emails. The approvers must be decided taking into account the content of the changes, for example if any of the updates are clinical in nature, then clinical approval is required, or if there is a change to collection of data then statistical approval will be required. A DMS representative must always be included on the approval list to document that they have assessed the impact of the change on data collection and database design. The trial team member completing the paper CRF/Worksheet finalisation checklist must also approve all changes.

It is recommended that the paper CRF/eCRF Approval template is used to record this approval, but it may also be in another format e.g. in the form of emails or meeting minutes. Evidence of approval by all relevant parties for each new CRF version must be gathered and stored in the Trial Master File.

Type of form	Where is approval documented?
Paper CRF	CRF Approval template
eCRF	eCRF Approval template
Worksheet	The eCRFs are approved and confirmation that the worksheet matches the relevant eCRFs is documented in the Worksheet Finalisation Checklist

See the CRF & eCRF Approval templates in SOPbox.

It is recommended that paper CRFs or worksheets are not be finalised and up-versioned until any related database testing has been completed successfully. This is to ensure that any required changes that arise during testing are incorporated into these documents prior to release to sites.

3.12 CRF/WORKSHEET VERSION CONTROL

CRFs/worksheets must be version controlled in line with the Document Management and Version Control Policy. It is important to ensure that during the development process each draft of a CRF/worksheet has an associated draft number and date.

See the Document Management and Version Control Policy and Versioning and Revision History WI in SOPbox for further guidance on versioning systems.

It is recommended that studies electronically highlight any new changes between drafts, e.g. by using different colour text.

See the Documenting CRF Changes WI in SOPbox for further guidance on how to achieve this.

CRFs/worksheets are likely to change throughout the life of a study. Therefore, each CRF/worksheet must be version controlled individually. The version history of study CRFs and worksheets (including the version number, release date, a summary of changes between versions and why these changes were made), must be maintained by the study team and made available to site staff. The Worksheet Version History document must include which eCRF versions are related to each Worksheet version. Depending on the study documentation, it may be easiest for this to be included and maintained within the CRF/eCRF Completion Guidelines document.

See the Paper CRF/Worksheet Version History templates in SOPbox

The eCRF version history (including the eCRF version with the database version) is expected to be maintained by DMS within the DMS master file, but may be incorporated into other version history documentation maintained outside of DMS.

3.12.1 CRF VERSION CONTROL FOR INTERNATIONAL STUDIES

In international studies, there may be a need to maintain multiple versions of the protocol and CRFs. Where this is the case, it must be clear to sites which version of the documents they are working to and there must be robust processes in place to ensure these are managed appropriately by the TMT.

3.13 CRF COMPLETION GUIDELINES

Each study must create a set of guidelines, which are provided to sites detailing how to complete CRFs. These guidelines may be provided as CRF/eCRF Completion Guidelines, Data Provision/Entry Guidelines, or alternative document.

See CRF Completion Guidelines template in SOPbox

These must be updated as and when any changes are made to the CRFs.

3.14 UPDATING CRFS DURING AN ONGOING STUDY

CRFs may be revised during an ongoing study for a number of reasons, such as:

- Protocol changes
- Errors in CRF design
- Common responses to an 'If Other, please specify' question being added as new category options
- Closing recruitment to a comparison

Whenever the study protocol is updated, the Protocol Data Collection Assessment spreadsheet (see section 3.3.2 of this SOP) must also be updated by the trial team ensuring input from a Data Scientist and Statistician, and clinical input if the updates are clinical in nature. This will ensure that any required CRF and database changes are implemented appropriately. The updated version of this document must be formally approved by the Clinical Project Manager (or delegate) and Statistician (and a clinician if the updates are clinical). Any relevant CRF and/or worksheet updates must be made before the new version of the protocol is released to sites. The updated CRFs and/or worksheets are not expected to be circulated to sites until the updated version of the protocol is released to sites unless site/country specific review or translation is required.

Any revisions to CRFs must be made following the processes described in this SOP.

3.15 RELEASE OF NEW CRF/WORKSHEET VERSIONS

New versions of CRFs/Worksheets will have an associated release date, which must be documented in the Paper CRF/Worksheet Version History document, along with a record of which protocol version each CRF/Worksheet version to which it is associated.

Where protocol/CRF approval may have different timelines in different countries/sites (as applicable), it is the trial team's responsibility to document individual site/country approval in the TMF (as in section 3.12.1).

In an eDC/rDC setting where protocol/CRF approval may have different timelines in different countries/sites, it is the trial team's responsibility to inform DMS when each country/site has approved using the new versions of eCRFs/Worksheets.

Some CRF versions may be associated with specific changes in the protocol e.g. if CRFs are updated for a protocol amendment. If this is the case, the CRF/Worksheet version that was current with the specific requirement at the time of the visit is expected to be completed, even if the CRF/Worksheet is completed at a later date.

If the site submits a CRF version collecting data associated with a protocol version that was not effective at the time of the visit, they should be asked to resubmit the information using an effective CRF version. If the only differences between the CRF versions submitted versus the effective CRF version at the time of the visit are not related to protocol-mandated data collection (e.g., a minor guidance change or additional trial management question added) the decision to accept a non-effective version can be made by the trial team.

Study teams must ensure that any appropriate documents, such as CRF Completion Guidelines or Data Provision Guidelines are updated following the release of new CRF versions, ideally being released at the same time as the CRFs.

4 RELATED DOCUMENTS

For further information on this topic, see also:

- MRC CTU SOP 058 Management of Participant Personal Data SOP
- MRC CTU SOP 090 Data Receipt and Entry SOP
- MRC CTU POL 004 Document Management and Version Control Policy
- MRC CTU WI 0079 Defining CRFs and CRF questions
- MRC CTU WI 0064 Versioning & Revision History
- MRC CTU WI 0061 Documenting CRF Changes
- MRC CTU TT 0153 CRF Template (Date format dd-mm-yyyy)
- MRC CTU TT 0154 CRF Template (Date format dd-mmm-yyyy)
- MRC CTU TT 0156 CRF Question Kit
- MRC CTU TT 0286 CRF Completion Guidelines Template
- MRC CTU TT 0296 Paper CRF Finalisation Checklist Template
- MRC CTU TT 0495 Worksheet Finalisation Checklist Template
- MRC CTU TT 0153 Paper CRF Version History Template
- MRC CTU TT 0494 Worksheet Version History Template
- MRC CTU TT 0493 Paper CRF Approval Template
- MRC CTU TT 0492 eCRF Approval Template
- MRC CTU TT 0496 Protocol Data Collection Assessment Template
- MRC_CTU_TT_0163 Guidance Notes on Completion of SAE Form
- MRC_CTU_TT_0168 SAE form dd-mmm-yyyy Non Coded Categories
- MRC_CTU_TT_0167 SAE form dd-mm-yyyy_Categories -