



Standard Operating Procedures

5.23.2 CRF Completion ©2007

History			
Version	Date	Author	Reason
1.1	23 rd August 2007	B Fazekas	New procedure
1.2	16 th October 2007	B Fazekas	Update after David Currow review

Approval				
Version	Author	Signature	Approval Name	Approval Signature
1.2	B Fazekas	<i>B. Fazekas</i>	D Currow (CI)	<i>David Currow</i>

Scheduled review

Date August 2009

Responsible person PaCCSC Project Officer

5.23.2 CRF Completion

Purpose

CRF's are the main source of data collection and recording for clinical trials. Within PaCCSC a series of CRF's are used for each trial to enable data collection at specific time point.

The data contained within the CRF is transferred to a data base to enable the data to be analysed and reported.

The accuracy of the data entered into the database is crucial, and is checked against the paper CRF. It is vital therefore that the paper-based CRF is an accurate, complete and contemporaneous (completed at the time of collection) reflection of the data.

This SOP details the process by which this will occur.

Other related SOPs

Electronic Data Handling

Attachments

File Notes

References

Guideline for Good Clinical Practice ICH Harmonised Tripartite 1996 (accessed 250207)
<http://www.ich.org/LOB/media/MEDIA482.pdf>

Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95). Annotated with TGA comments 2000 (accessed 250207)
<http://www.tga.gov.au/docs/pdf/euguide/ich/ich13595.pdf>

Joint NHMRC/AVCC Statement and Guidelines on research practice 1997 (accessed 250207) <http://www.nhmrc.gov.au/funding/policy/researchprac.htm>

Definitions

Case Report Form (CRF)

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. All events described within the study protocol should be captured the CRF.

Journal Notes

Journal notes do not form protocol data, but when written within the participant study record can provide rich additional data to explain data held within the CRF. An example may be when quality of life is being measured and the participant has had a recent bereavement. A journal note can record the bereavement to explain why the QOL may record unexpected data. Journal notes do not replace study data recorded within the CRF.

File Notes

File notes are short documents that are used to explain discrepancies in data, deviations from protocol, and where sites have specific procedures that might vary from the study protocol, Examples may be;

- where there is a discrepancy between source documents and CRF entries,
- where source data cannot be located,
- where a deviation between randomisation request and allocation is found.

They serve to provide verification that data was collected and recorded according to established procedure.

Source Documents

Original documents, data and records (hospital records, clinical file charts, laboratory notes, diaries, checklists, dispensing records etc). These documents allow for reconstruction and evaluation of the trial. Data held within source documents are the first record of clinical observations. Examples include:

- pathology reports to confirm blood results used a eligibility screening
- clinical records charting patient clinical assessment, used to monitor patient eligibility or progress
- Dangerous Drug Accountability signature sheets to show correct checking and dispensing procedures
- CRF's where patient vital signs are recorded during a patient visit (this is particularly if this forms the only record of the vital signs and is not a transcription of vital signs recorded elsewhere)
- Quality of life forms completed as part of the study measures, and where this recording is the original or only recording of the QOL at that time.

Procedure

Responsibility

Site Study nurses

- Organise the CRF's in preparation for participant use
- Complete the CRF at protocol specific time points
- Ensure that the CRF's accurately reflect the data collected at each time point
- Ensures that the CRF has the associated source documents as described within the study protocol
- Prepares the CRF for data entry

Site Coordinators

- Reviews the CRF prior to data entry
- Enters the data into the electronic data base
- Responds to data queries raised during the checking procedures
- Ensures the CRF's are filed in accordance with Good Clinical Practice, both short and long term

Project Officer

- Develops the CRF in accordance with the investigator team instructions and requirements
- Ensures that the CRF is developed in such a way as to be;
 - Logical
 - Clear
 - Sequential
 - Complete
- Receives a copy of the CRF from the site coordinator following entry into the electronic data base
- Checks the CRF against the data base according to the Electronic data handling SOP

National Manager

- oversee the maintenance of the data collection and provide routine and ad hoc reports to the Management Advisory Board and Trial Management Committee when requested

General rules for CRF completion

- Use black or blue ball point pen, do not use pencil
- The CRF must be signed where required by the site investigator or the delegated sub-investigator to verify its accuracy, completion, and that the data was conducted in accordance with the study protocol.
 - This is usually required for eligibility screening to ensure that the participant meets all the criteria and are approved to participate
 - This may also be the case if specific medical review is required, such as review of response prior to changing the study drug dose.

- Complete ALL questions, blank fields indicate that data wasn't collected, or missed, most questions will have an appropriate response available, but in the case where this is not possible;
 - If a question does not apply, write N.A.
 - If a test is not done, write N.D.
 - If a result is zero, write 0.
- If an error is made, draw a SINGLE line through the error, write the correct entry in an adjacent space and INITIAL and DATE the correction.
- Do not use correction fluid, texta or other means of obliterating the original entry
- Pages must NOT be removed from this Case Report Form, unless otherwise instructed by the chief investigators.
- Dates must not be backdated. Late entries are acceptable. File notes can be used to explain this,
- Do not copy information onto a new clean page even if the CRF looks 'messy'
- Follow the specific instructions provided within study CRF's where provided

Specific rules to enable seamless data entry

- All dates are to be recorded in the following format
 - Dd/mmm/yyyy (eg, 03/jul/1923)
 - No other format is acceptable as the format may change during data download procedures.
- Checkboxes allow multiple choices to be recorded
- Radio buttons allow only one choice, and data entry is only possible for a single choice. If more than one response is made on the CRF there is no way the responses can be recorded. Attempts at multiple responses will result in missing data for the data point.
- Text Fields. There are cases when free text is required. The instructions for these questions should be followed carefully as there may be rules applied regarding data text. This may include the number of characters accepted by the data base on entry. In text fields, don not use paragraph breaks to separate pieces of text, use full stops, hyphens, colons to separate text.

Use of Journal Notes

There are circumstances where important (or potentially important) information is made available to study staff outside the specific data collection requirements. In this case recording of this information as a journal note is acceptable.

Each CRF has a blank page at then end (created as a result of printing from the data base). This page can be used to record journal notes.

Journal notes should be dated and initialled, and contain clear and concise text which succinctly describes the information being provided by the participant. A single line should be drawn under the text to indicate the end of a single field note as further field notes may be added later.

Examples of journal notes may be where the participant recalls specific events which may impact on the quality of the responses recorded, or when life events, such as bereavement, family visit, scheduled tests etc, may have an effect on the data being collected.

Sample Only



File note.

Purpose

File notes are to ensure that any changes or actions taken regarding the study are documented and are able to be authenticated by any member of the study team and monitors.

Any changes to data and study related documentation that does not have an associated file note is subject to suspicion and doubt, leading to possible exclusion of the participants data from the analysis.

Complete one of these forms for each and every change made to the recording of data that does not have a data query form.

Instructions

All of the following sections are to be completed by the person who made the change or another who can authenticate the change. The original is to be stored at the site of origin, a copy is to be forwarded to the Coordinating site or Central Registry (if related to randomisation for filing).

Note:

Date of change:

Changed from:

Changed to:

Changed by:

Date of File note:

Signature of person completing file note.

PaCCSC

File note.

Purpose

File notes are to ensure that any changes or actions taken regarding the study are documented and are able to be authenticated by any member of the study team and monitors.

Any changes to data and study related documentation that does not have an associated file note is subject to suspicion and doubt, leading to possible exclusion of the participants data from the analysis.

Complete one of these forms for each and every change made to the recording of data that does not have a data query form.

Instructions

All of the following sections are to be completed by the person who made the change or another who can authenticate the change. The original is to be stored at the site of origin, a copy is to be forwarded to the Coordinating site or Central Registry (if related to randomisation for filing).

Note:

Date of change:

Changed from:

Changed to:

Changed by:

Date of File note:

Signature of person completing file note.