UTS IMPACCT Trials Coordination Centre

Standard Operating Procedure

5.23.2 Data Collection Worksheet Completion

Version	V2.4
Author/s	J Hao
Approved	M Agar
Effective date	01/04/2022
Review date	01/04/2024

DO NOT USE THIS SOP IN PRINTED FORM WITHOUT FIRST CHECKING IT IS THE LATEST VERSION AS AVAILABLE FROM www.uts.edu.au/itcc

Introduction/Background

Case Report Forms (CRFs) are the main source of data collection and recording for clinical studies. A series of paper worksheets and electronic CRFs (eCRFs) are used for each study to enable data collection at specific time points.

The study data contained within the paper data collection worksheets and other source documents is entered into eCRFs in an electronic database and used for data analysis and reporting.

Data collection worksheets are designed to capture required data and to enable smooth data entry in electronic case report forms (eCRFs) through similar question and response structures to minimise data entry errors.

The accuracy of the data entered into the database is crucial and is checked against the data collection worksheet and other relevant source documents. The worksheet must be an accurate, complete, and contemporary (completed at the time of collection) reflection of the data.

These worksheets may be considered source documentation, where the worksheet is the first recording of study data.

Objective

This SOP details the process by which data collection worksheets and eCRFs are completed.

Scope

This SOP applies to all staff involved in clinical studies conducted by the IMPACCT Trials Coordination Centre (ITCC), including Palliative Care Clinical Studies Collaborative (PaCCSC) and Cancer Symptom Trials (CST), irrespective of individual organisational employment, role, or position.

Ownership and Responsibility

Authorisation to complete data collection worksheets and eCRFs is a responsibility delegated by the Principal Investigator and must be recorded in the Staff Signature and Delegation Log (*refer* SOP 4.2.4 Delegation of Duties), prior to the task being undertaken, and only after the designee has completed the relevant study related training. The responsibility remains with the Principal Investigator.

Responsibilities of the Principal Investigator (or delegate)

- To review the data collection worksheet prior to data entry in the eCRF
- To enter the data into the eCRF within the electronic database
- To respond to data queries raised during subsequent checking procedures
- To ensure the paper worksheets are filed and stored in accordance with GCP, both short and long term

Responsibilities of the study site team members

- To organise the data collection worksheets in preparation for participant use
- To complete the data collection worksheets at the protocol specified time points
- To ensure that the worksheets and eCRFs accurately reflect the data collected at each time point
- To ensure that the eCRFs have the associated source documents as described within the study protocol
- To prepare the data collection worksheets for data entry into the eCRF.

Responsibilities of the ITCC National Project Officer (or delegate)

- To develop the data collection worksheets and eCRFs according to the study protocol, and the investigator team instructions and requirements
- To ensure that the data collection worksheets and eCRFs are developed in such a way as to be:
    - logical
    - clear
    - sequential
    - complete
- To develop and follow the Data Management Plan for the study (Template 10)
- To develop and follow the Monitoring Plan for the study (Template 35)
- To monitor data collection, entry and completion via the data management plan and monitoring plan for the individual studies
- To receive a copy of the completed data collection worksheets from the Principal Investigator (or delegate) following entry into the eCRF in the electronic database, along with any other documents where the recording is entered into the database (such as questionnaires, assessment tools, etc., but not medical record notations, and all by PID only)

Responsibilities of the PaCCSC/CST National Manager

- To oversee the maintenance of the data collection and provide routine and ad hoc reports to the relevant Scientific Advisory Committee when requested

Procedure

1. Data collection worksheets

- The Principal Investigator should ensure the accuracy, completeness, legibility, and timeliness of the data reported to the Sponsor in the eCRFs and in all required reports.
- Where specified in the study protocol, eCRFs may be considered source documentation, where the eCRF is the first recording of study data, such as during study visits where there are no other traditional source documents. For example, if questionnaires or surveys are completed and submitted electronically by participants using a tablet or computer.
- To assist sites in ensuring that source documentation and data reported in the eCRFs are complete and consistent, ITCC develops and provides study specific data collection worksheets for use. The worksheets are designed to capture the required data and to enable smooth data entry in the eCRFs through similar question and response structures to minimise data entry errors. These worksheets may be considered source documentation, where the worksheet is the first recording of study data. For example, to document the results of a protocol specific measure which might not be routinely done in clinical practice and would not be typically noted in the medical records (*refer* SOP 4.9.2 Source Data and Documentation).
- The data within the worksheets and eCRF must be supported by other corroborating information, such as admission records, recording of adverse events, clinical visits as applicable.
- Data collection worksheets should be completed according to the specifications of each study, prospectively and where possible as close to the study visit as possible. If the worksheet is the source document, it must be completed contemporaneously at the same time the assessment occurs/study measures are performed.
- All entries on the data collection worksheets must be accurate and legible. All data entered in the eCRF must be verifiable with source data from the participant's data collection worksheets, medical records, and other relevant documents as applicable. Any discrepancies between the eCRF and the source data should be explained and documented.
- The participant's identity should remain confidential. The participant should only be identified on the worksheets and eCRFs by means of their allocated study ID number, this includes Serious Adverse Event Reports and other forms of reports and logs
- Participant data collection worksheets should be kept in a secure location during the course of the study. On completion of the study, the paper worksheets should be archived as per study protocol (*refer* SOP 8.4.1 Archiving).

2. Data collection worksheet completion

2.1. General rules for paper worksheet completion

- Use black or blue ball point pen, do not use pencil.
- The worksheet is signed where required by the Principal Investigator (or delegate) to verify its accuracy, completion, and that the data was collected in accordance with the study protocol.
    - This is required for eligibility screening to ensure that the participant meets all the criteria and is approved to participate, at cessation of treatment and at participant withdrawal.
    - This may also be required because of a specific medical review, such as review of response prior to changing the study drug dose.
- Complete ALL questions; blank fields indicate that data was not collected or missed. Most questions 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 and provide a reason.
    - 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.
- Do not write over the initial entry in such a way that the initial entry is unclear.
- All worksheets must be paginated (e.g. Page 1 of 3) and have a record of the protocol name/number, participant ID and date of the visit/contact.
- Participant ID must follow ‘Study code/Site code/ID number: _ _/ _ _ _/ _ _ _’.
- Do not contain any personally identifiable information such as name or hospital record number.
- Pages must NOT be removed from the worksheet (blank or otherwise), unless otherwise instructed by the study investigators.
- Dates must not be backdated. Late entries are acceptable but must be initialled and dated at the time the entry is made and with reference to the actual date of completion, 'For: date'. (E.g. N.S 23Jan2020, *for 15Dec2019*). Notations within the data collection worksheet and eCRF can be used to explain the reason for the late entry.
- All quality of life or other participant/site staff completed questionnaires and forms completed as part of the study measures that are separate to the worksheets must also have a record of the protocol name/number, participant ID and date of completion.
- Do not copy information onto a new clean page even if the worksheet looks ‘messy’.
- Follow any specific instructions that may have been provided within the study worksheet.
- Data in the worksheets needs to be supported by other corroborating information, such as admission records, recording of adverse events, clinical visits as applicable.
- Additional notes written into the worksheet do not form part of the data entered into the

eCRF but may be helpful to add as notes within the eCRF if required or to explain the data. Additional notes should not be written with the intention of being the data.

- Store the participant data collection worksheets in a secure location.
- A copy of the original data collection worksheet should be forwarded to the ITCC to enable verification of data entry and for filing.

2.2. Specific rules to enable seamless data entry in the eCRF

- Data entry is limited to designated study staff trained and experienced in transcribing data for this purpose.
- Data from participants' visits should be entered into the eCRF within 5 business days from the visit.
- All dates are recorded in the format specific to the RDMS for that study (*refer* SOP 5.1.1 Electronic Data Handling):
    - Use the 'date picker option' if provided
- No personally identifying information will be entered into REDCap at any time.
- Specific care is to be taken when recording clinical information such as notes within Serious Adverse Events.
- Checkboxes – these allow multiple choices to be recorded.
- Radio buttons – these allow only one choice, and data entry is only possible for a single choice. If more than one response is made on the data collection worksheet, it is not possible for other responses to be recorded in the eCRF. Attempts at multiple responses result in missing data for the data point. Participants are clearly instructed to choose ONLY one option for these questions on the paper worksheet.
- Text fields – there are cases when free text is required. The data collection worksheet instructions for these questions should be followed carefully as there may be rules applied regarding data text in the eCRF. This may include the number of characters accepted by the database on entry. In text fields, do not use paragraph breaks to separate pieces of text; use full stops, hyphens, or colons to separate text.
- Calculation fields – these perform calculations based on other data in a record. Variable names are used to define an equation. Once the data for those variables has been entered, REDCap will execute the calculation and display the calculated value on the form.
- File upload fields – these allows a site user to upload their own file for ITCC to download.

2.3. General rules for missing data identification

Missing values may be due to interruptions of the data flow or the unavailability of the target information. It is essential to understand the difference between "handling missing data" for data cleaning purposes.

Handling missing data for data cleaning purposes must answer the following two questions:

1. Were missing data collected on eCRFs?
2. Were missing data lost during database manipulations?

If the missing data were not collected on the eCRF, it is possible to create a query in order to replace the missing value. The queries that arise during the data reconciliation should be handled in the same manner in which clinical queries are handled.

If the missing data were lost during database manipulations, replacing the missing value with the original value (source data) is necessary.

In the REDCap EDC system, fields that have a blank/missing value may be marked with a custom 'Missing Data Code' to note why the value is blank. These missing codes may be used to aid in data analysis by specifying why a field lacks a value.

The REDCap EDC system missing data codes for its setting up and implementation are shown in Table 1 below.

Table 1. REDCap EDC system missing data codes

Missing Data Codes	Definition
DTH	Missing data due to death
DPRO	Missing data due to disease progression unrelated to the trial (i.e. the person became more unwell due to their underlying condition but it is specifically not thought to be related to the trial itself - This should ideally be signed off by the local PI)
AEI	Missing data due to adverse events/reactions related to the intervention
RPO	Missing data related to the primary outcome (i.e. due to the participant being in more pain, less pain or they don't feel the pain has improved so chose to leave fields blank/leave trial)
PMQ	Participant missed question by accident
RFQ	Research staff forgot to ask/fill out field
QUB	Missing data due to question burden (i.e. Participant thought there were too many questions to fill out and did not want to complete question)
MEM	Missing data due to participants' mental/emotional health
NA	Not Applicable

Related SOPs

4.2.4 Delegation of Duties

4.5.3 File Notes

4.9.2 Source Data and Documentation

5.5.1 Electronic Data Handling

8.4.1 Archiving

Related documents

Study Protocol

Template 10: Data Management Plan (study specific)

Template 35: Study Monitoring Plan (study specific)

References

Australian Code for the Responsible Conduct of Research 2018 (accessed 07/02/2020) https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2). November 2016 (accessed 23/10/2017)

https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2__Step_4.pdf

Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95). Annotated with TGA comments 2000 (accessed 17/10/2017)

https://www.tga.gov.au/sites/default/files/ich13595an.pdf

Praxis

History			
Version	Date	Author	Reason
1.1	23/08/2007	B Fazekas	New procedure
1.2	16/10/2007	B Fazekas	Update after David Currow review
1.3	9/06/2010	B Fazekas	Periodic review
2.0	3/02/2011	B Fazekas	Changes ratified by the MAB
2.1	20/05/2015	C Hope	Periodic review
2.2	28/02/2018	B Fazekas, S Kochovska	Periodic review Publication of the ICH GCP E6 (R2)
2.3	16/03/2020	C Strauss	Periodic review SOP renamed in accordance with updated terminology for data collection worksheets and eCRFs.
2.4	02/12/2021	J Hao	Periodic review

Approval		
Version	Approval Name	Approval Signature
2.4	M Agar