Standard Operating Procedure

4.9.2 Source Data and Documentation

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Introduction/Background

Source data and documentation is identifiable data that verifies the information contained within the study Case Report Forms (CRFs). Copies of source data and documentation are not held by the study site or IMPACCT Trials Coordination Centre (ITCC); they are accessed at the site during monitoring and auditing visits.

A statement of permission to access source data for regulatory and audit purposes is included within the Participant Information and Consent Form for the study, with explicit explanation of this given as part of the consent process.

Source data are usually found in the participant's medical record file. Source data include (but are not limited to):

- medical assessment notes
- progress notes/records
- medication chart
- medical letters/correspondence
- investigational reports (for example, pathology, x-ray, spirometry, echocardiogram etc.)

The International Conference on Harmonisation of Good Clinical Practice (ICH GCP) guidelines specify that source documents may also include the data recorded within CRFs (or contained on audiotapes) if these data form clinical data from which analysis is conducted, are not contained within other source documents, and are specified within the study protocol. For example, if clinical observations are recorded within the CRF and used as study data, this is then source data.

The purpose of source data and documentation are:

- confirmation of unidentified data to protect the integrity of the study results. For example, a diagnosis given in a medical assessment notation in the clinical record can verify the diagnosis information in a CRF.
- substantiation that proper and due process was followed. For example, description of the consent process in the clinical record can confirm that proper consent process was followed and that the consent form was verified.
- safety of the participant. For example, documentation of study activity in the clinical record provides information about the study to other clinicians involved in the care of the participant, and that problems reported in the clinical record are accurately reflected in the CRF.

Objective

This SOP describes the requirements for source data and the processes for accessing source data and documentation when required.

Scope

This SOP applies to all staff involved in clinical studies conducted by the IMPACCT Trials Coordination Centre (ITCC) irrespective of individual organisational employment, role, or position. All staff responsible for caring for a patient on a clinical trial may contribute to clinical trial source data.

Ownership and Responsibility

Responsibilities of the Coordinating Principal Investigator

- To articulate the source data and documentation requirements in the study protocol
- To review source data and documentation as and if required

Responsibilities of the Principal Investigator (or delegate) as documented on the Staff Signature and Delegation Log (refer SOP 4.2.2 Delegation of Duties)

- To ensure source data and documentation is collected / completed as per the protocol
- To ensure all source documents contain the participants name or Participant Identification Number (PID) and date the document was generated
- To record all study related activities with the participant in their clinical or progress notes
- To ensure source data and documentation are stored securely and available for review during monitoring and auditing visits, in accordance with local hospital/service policy
- To provide source data and documentation to the Human Research Ethics Committee (HREC) and the Data Monitoring and Safety Committee (DMSC) as and if required

Responsibilities of the ITCC

- To provide sufficient notice of monitoring and auditing visits to study sites
- To provide data collection worksheets to assist sites with source data and documentation
- To provide direction and advice on source data and documentation to sites
- To monitor source documentation as part of routine study monitoring process

Procedure

1. Source data

Participants for ITCC studies are often assessed within environments where other traditional source documentation may not be present. These environments may include:

- participant's own home;
- residential aged care facility;
- hospice or palliative care unit where some study requirements are not collected.

For each study, the ITCC develops and creates data collection worksheets to assist sites with source data documentation to ensure source data is complete and includes all data points collected in the electronic CRFs. The ITCC therefore considers that much of the data within the worksheets are the first, and often the only record, of observations or assessments. In these circumstances, the data within the worksheet is source data, and there is no requirement to subsequently duplicate the data into another record for the purpose of generating source data.

The Principal Investigator should maintain adequate and accurate source documents and trial records that include all pertinent observations on each of the site's trial subjects. Source data should be:

- attributable – it should be clear who made the entry
- legible – the entry must be readable
- contemporaneous – the entry must indicate both when the event occurred as well as when it was entered
- original – the entry must be the first place the information was recorded
- accurate – the entry must reflect what occurred
- complete – the entry must be complete, with no missing data
- In addition, any changes to source data must be traceable, should not obscure the original entry and should be explained if necessary.
- At ITCC, Guidance 2 (Documentation of Consent) is used for all patients who participate in a clinical trial to record specific visits, and for both electronic and paper medical records.

Source documents and participant study records must be stored securely at the site and measures taken to prevent accidental or premature destruction of these documents and to ensure that participant privacy and confidentiality are maintained. Access to study records including source documents must be restricted to study site staff only and made readily available for review upon the request of the Sponsor, monitor, auditor, HREC, or regulatory authority.

Source documents are frequently filed separately to the Investigator Site File, for example pathology reports, referral letters and progress notations which are typically stored within the

participant's medical records. Source data location and access is to be recorded in a log that is filed in a prominent position in the Investigator Site File (*refer* to SOP 8.0 Essential Documents). The Essential Documents Log (Template 11) provides an example of how such a log may look and how to complete it for various types of source documents.

The following describes the procedures for accessing source documents when required.

1.1. Clinical notes versus progress notes

The ITCC recognises that some home-based (community) participants may not have clinical notes in which to record study activity. In such circumstances, the Principal Investigator (or delegate) is to document all study activity relating to the participant in progress note format.

- The progress notes must include the record number of the participant, date of the activity and the name (and signature, if in written form) of the study team member writing the notation (r*efer* Guidance 2: Documentation of Consent).
- If it is the site's policy, written (hard copy) notes and other personally identifying records (e.g., signed consent form, medical assessment notes, medication chart, pathology reports etc.) can be stored separately from the participant's study file to avoid potential re-identification of participants.
- A copy of the progress notes must be submitted to the organisation's Medical Record Department for inclusion in the participant's medical record.

2. Monitoring / Auditing Visits

- The ITCC Monitor arranges to visit the site as per SOP 5.18 Monitoring.
- A minimum of 2 weeks' notice of visit (and Participant Identification Numbers being monitored) is given to ensure sufficient time to obtain access to source documents.

2.1. Accessing paper (hard copy) clinical documentation

- The Principal Investigator (or delegate) arranges for the clinical files containing all source documents (related to the participants being monitored) to be available during the monitoring visit.

2.2. Accessing electronic (soft copy) clinical documentation

- Ideally, the monitor/auditor views the electronic documents on screen during the visit.
- Access to the electronic documents is determined according to local hospital/service policy. Options for access are:
    - The Principal Investigator (or delegate) arranges an individual 'log on' to the system, for the monitor prior to the visit. The monitor should only be able to access the clinical files of the participants being monitored.
    - In the event that the above contravenes local hospital/service policy, the Principal Investigator (or delegate) may sit with the monitor during the visit and access the clinical files using their own access 'log on'.
- If neither of the above options is possible, the Principal Investigator (or delegate) may print off the electronic source documents and provide them to the monitor for review.

Printed electronic source documents are only accepted when they include the participants name or PID and the date the document was generated. The print-out of the electronic source document must also be certified by the person who generated the document (by a dated signature) to confirm that it is an accurate and exact copy of the original.

- Hard copies of electronic source documents can be certified by either a signed and dated written statement on the front page of the paper copy (e.g., “I, [name], certify that this document (X pages in total) is an accurate and exact copy of the original”) or through the use of a validated process (e.g., a stamp). All pages of the certified copy must be paginated and secured.

- The Principal Investigator (or delegate) must be available to provide further (missing) source documents required by the monitor during the visit. Failure to do so may result in corrective actions and/or incomplete monitoring.

3. Request from the Data Monitoring and Safety Committee (DMSC), or Medical Monitor (MM)

- The ITCC informs the Principal Investigator what specific source documents are required for review by the DSMC or MM.
- When possible, the Principal Investigator (or delegate) will send copies of the required source documents to ITCC via secure email. All personal identifying information must be redacted from the source documents prior to sending the copies to the ITCC.
- If necessary, a delegate of the DSMC or the MM may visit the site and review the source documents in person, following the procedures set out above.

Related SOPs

4.2.4 Delegation of Duties

5.18 Monitoring

8.0 Essential Documents

Related documents

Guidance 2: Documentation of Consent (example)

Template 11. Essential Documents Log

References

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

National Statement on Ethical Conduct in Human Research (2007)- Updated 2018- (accessed 07/02/2020)

https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018

Praxis Australia

History			
Version	Date	Author	Reason
1.0	7/07/2015	C Hope	New procedure
1.1	28/02/2018	B Fazekas, S Kochovska	Periodic review Publication of the ICH GCP E6 (R2)
1.2	16/03/2020	C Strauss	Periodic review Publication of the National Statement on Ethical Conduct in Human Research (2007) - updated 2018
1.3	04/01/2022	C Strauss	Periodic review

Approval		
Version	Approval Name	Approval Signature
1.3	Meera Agar