Great Western Hospitals NHS
NHS Foundation Trust

Standard Operating Procedure: Source Data and Documentation and Case report form completion

SOP NUMBER:002 Version Number & Date: 1 dated 14/10/2016 Superseded Version Number & Date(if applicable):	Effective Date: 14/10/2016 Review Date: 01/04/2018

Author:

Name: Suzannah Pegler Position: Lead Research Practitioner Signature:_____
Date: 14/10/2016

Approved by:

Name: Catherine Lewis-Clarke Position: R&I Manager Signature:_____
Date: 14/10/2016

Name: Dr E Price Position: R&I Director Signature:_____
Date:14/10/2016

BACKGROUND

ICH Good Clinical Practice Guidelines defines Source data as

"All Information in original records and certified copies of original record of clinical findings, observations or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial.
Source data are contained in source documents."

Source data are the first record of any interactions with participants and any data relating to them.

ICH Good Clinical Practice Guidelines 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"

The rationale for using CRFs in a study is to collect the necessary information about:

- The patient
- Study interventions
- Administration of the Investigational Product (if applicable)
- Study procedures
- Outcome of assessments/tests
- Adverse events

CRFs are the official documentation of the trial for both sponsors and regulatory authorities, and together with the source documents will be closely examined during audits and inspections.

The data gathered in the source documentation and subsequently collected on the CRF is used directly as the basis for the trial report and any publications, as well as making up part of the data for regulatory approval of a new drug. It is the evidence for the research outcomes.

PURPOSE

To describe the procedure for the documentation and collection of source data and the completing, signing and correcting of case report forms.

Clear communication and documentation is vital to the safety of the patient and the integrity of the trial.

PROCEDURE

1. WHO?

All clinical and non-clinical information and procedures must be documented by clinicians/healthcare professionals involved with the individual participant.

The delegation of responsibility of data collection and CRF completion by the Investigator should be documented on the Study Delegation Log/ Site Responsibility Log (title of form can vary from centre to centre) and only these Individuals may enter data in a CRF.

2. WHEN?

Source data should be documented for any clinical/non clinical interaction with the participant as soon as possible following that interaction.

CRFs should be completed according to the specifications of each study and will often come with guidelines for completion.

CRFs should be completed in a timely fashion and where possible within 5 working days.

3. HOW?

- Always use a black ink ballpoint pen.
- Ensure all entries are accurate, legible and verifiable. Do not invent data.
- Source documentation should include the study name and patient identifiable number. On-going willingness to continue in the study, general wellbeing, concomitant medications, medical reviews, abnormal findings, changes to treatment, assessment results and visit schedule should all be recorded. Sponsors may give specific guidelines on what specific information to document.
- Ensure data entry is as complete as possible without omissions. It is impossible for personnel doing the data entry to interpret blank spaces. If data are unavailable write, for example, '*unknown', 'missing', 'test not done',* etc as defined by CRF Completion Guidelines (if applicable). Avoid using the ambiguous phrase, *'not available'*.
- Ensure dates are clear and legible and follow the format required by the sponsor [i.e. DD/MON/YYYY]
- Never over-write an entry. Corrections should be made as follows:
  - Cross out the incorrect entry with a single line so that the incorrect entry should still be readable. Never use correction fluid or obliterate entries made on source documents or CRF.
  - Enter the correct data.
  - Initial and date the correction.
- Electronic source data should be printed out and signed to certify the copy and filed within the patient's notes for verification purposes. Read only access may be granted to monitors to view and verify electronic access – see Monitoring SOP.
- If the CRF's are paper, complete legibly, photocopy and send [original or copies] to the sponsor as directed and file a set in the patients' medical records.

- If the CRFs are electronic, only designated individuals will input data onto the systems following training and authorisation from the sponsor.

- If the CRFs are printed on carbonless duplication paper, always make sure that a suitable separator is inserted under the form being completed.

- Any discrepancies with source data should be explained and the significance noted in the CRF and/or patients medical records. For laboratory values outside the laboratory's reference range or some other range agreed with the study Sponsor, or if a value shows significant variation from one assessment to the next, this should be commented on and the significance noted in the CRF and/or patients medical records.

- Some studies will provide source document templates or allow patient data to be entered straight onto a CRF – check the study requirements and REC permissions – it is good practice to record data in the patients' medical records also.

- The procedure to be followed for the resolution of data queries should be agreed with the study sponsor and completed by site staff in a timely fashion.

- Unless otherwise agreed, laboratory values should be entered without conversion from printed reports even if in multi-centre study units of measurement differ from centre to centre.

- The patients' identity should remain confidential at all times, for this reason it is imperative that the patient is identified by a study number and/or initials only on the CRF. A record must be kept by the Investigator of patients in the study consisting of the patient's full name and study number; this is the Subject Identification Log.

- The CRF must be signed where indicated, by the Principal Investigator or designee (as appropriate) to assert that he/she believes they are complete and correct.

- CRFs should be kept in a secure location during the course of the study. CRFs should then be archived when the study has finished.

4. APPENDICES

NIL