1. BACKGROUND

ICH Good Clinical Practice Guidelines define a case report (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 rational 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

CRF’s 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 collected on the CRF is therefore 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.
2. PURPOSE

To describe the procedure for completing, signing and correcting case report forms.

3. PROCEDURE

3.1 Who?

Prior to study initiation / start up, it is the responsibility of the principal investigator to ensure that there is an adequate supply of CRF’s at the research site to conduct the study. The designation of the responsibility of CRF completion by the investigator should be documented on the delegation log and only these individuals may enter data in a CRF.

3.2 When?

CRFs should be completed according to the specifications of each study, prospectively in a timely fashion where possible.

3.3 How?

1. Record keeping should be undertaken in line with hospital policy and the MNC guidelines on record keeping.

2. Use black ink only.

3. If the CRFs are printed on carbonless duplication paper always make sure that a suitable separator is inserted under the form being completed. Carbonised copies must be legible.

4. Ensure data entry is as complete as possible. Do not leave blank spaces: It is impossible for personnel doing the data entry to interpret blank spaces. If data is unavailable write unknown, and explain the reason why it is not available e.g. missing date or test not done, as appropriate. Avoid using the ambiguous phase, not available.

5. Ensure all entries are accurate, legible and verifiable with the source data in the medical record. All data being entered onto the CRF must have been recorded in the patient’s hospital notes.

6. 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.
7. Corrections should be crossed out with a single line, signed/initialled and dated. The original entry must be readable, NEVER use correction fluid.

8. 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.

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

10. CRFs should be filled in as per requirements of the main centre. Personally identifiable information such as the patient’s full name or address should not be recorded unless specifically required by the trial centre.

11. Where records are faxed, a cover sheet should always be used. If the CRFs are returned by post, the envelope must be marked ‘Private and Confidential’ and include the sender’s address.

12. The CRF must be signed where indicated, by the principal investigator or designee to assert that he/she believes they are complete and correct.

13. The results of investigations and lab tests should be reviewed by a clinician on the delegation log before they are recorded in the CRF. The report should be printed, provided to the clinician for initialling, and subsequently filed in the patient’s hospital notes.

14. Any deviations from the protocol, or other unusual events, should be fully explained on the CRF. This would include discussions held with the study centre regarding the CRF data, or that the consent was gained through an interpreter. This will ensure that the study can be reconstructed at a later date if necessary.

4. OTHER RELATED PROCEDURES

Study files and filing
Archiving and destroying documents

5. REFERENCES AND FURTHER READING

ICH Harmonised Tripartite Guideline for Good Clinical Practice (1996)


Much of the text of this SOP has been adapted from:

6. APPENDICES