

	Standard Operating Procedures
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Procedure Category:	Document Management and Storage
Procedure CLN-05-02:	Case Report Forms

Procedure Overview

This procedure describes the necessary tasks in completing and maintaining case report forms.

Responsible Individuals

Qualified MICHHR personnel (including, but not limited to, Study Coordinator and Research Assistant); Investigator; Director, MICHHR

Procedure

The following items define basic guidelines that apply to handling case report forms (CRFs).

1. All entries on the CRFs must be completed legibly using a black ballpoint pen, typewriter or an approved automated system.
2. Only acceptable medical terminology and standard abbreviations should be used. Refer to institutional abbreviations for approved standards.
3. Care must be taken to avoid accidentally recording information on CRFs if multipart paper is utilized.
4. Clock times are normally entered in 24 hour format.
5. Dates are normally indicated by one of two formats: 10-01-2001 or 01/OCT/2001. Please refer to the sponsor's case report form guidelines.
6. Blank spaces, question marks, or zeros are not to be used for unknown information. The following abbreviations are normally used to indicate missing information:
 - N/Av: Not Available.
 - N/A: Not Applicable
 - N/D: Not Done
 - Single slash marks

Please refer to the sponsor's CRF guidelines.

7. Each item is to be answered or checked individually rather than by using vertical lines or ditto marks to indicate a series of identical answers.
8. All discrepancies or missing data noted during a Protocol Review and/or Monitoring Visit are to be resolved by MICHHR personnel before the data is forwarded to the sponsor/CRO.
9. CRF corrections are to be made in the following manner:

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Approval Signature, Date:	

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- a) The original entry will be lined out with a single line drawn through the error so that it remains legible. (Do not erase, write over, or use corrective fluid).
 - b) The correction is recorded in black ink and initialed and dated by the person making the correction. An approved abbreviated reason may be recorded next to the correction (e.g. ee = entry error, oe= omission error). Please see the sponsor CRF guidelines for reference.
 - c) Only the investigator or designee for a specific study can record corrections on original CRFs.
10. MICHIR personnel ensure, if possible that forms are available, completed, dated and signed by the investigator or designee within one week of study subject visits.
11. In the event that the sponsor and/or CRO request data clarifications (DCF) after the original CRF has been submitted, MICHIR personnel complete the following tasks:
- a) Retrieve or requisition the relevant source documents
 - b) Identify the appropriate information
 - c) Enter the correct information on the DCF with a black pen or typewriter
 - d) Initial and date the DCF correction
 - e) Indicate the reason for the correction or clarification on the DCF


Notes:

- DCF corrections and clarifications are not made directly on the site copy of the original CRF.
- DCF corrections and clarifications are submitted to the sponsor and/or CRO within one week of receipt via mail or fax.
- DCF originals and/or copies are filed in the subject's CRF notebook.

Documentation

Documentation for this procedure includes documentation generated by the CRFs, Quality Improvement Coordinator report, Sponsor and/or CRO monitoring communications

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Relevant Definitions

Not available (N/Av) - this term is used when the data are not available because they are not retrievable, the subject cannot remember, or the data was lost.

Not applicable (N/A) - this term is used for data that do not apply to the subject. For example, if the CRF requests a pregnancy test and the subject is a man, "N/A" should be recorded.

Not done (N/D) - this term is used when data were not obtained. For example, if a vital sign such as blood pressure was requested but was not measured, record "N/D".

Deviation Approval

The Director, MICHIR or designee, must approve deviation from this procedure. The Director, MICHIR or designee, must store documentation of the deviation approval.

Procedure Author

Manager, Research Support Core

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