

<b>Title</b>	<b>How to Fill In a Case Report Form and Modify Data</b>
<b>Code</b>	SOP-25
<b>Pages</b>	7

**History of Validated Versions**

<b>Date</b> dd/mm/yyyy	<b>Version</b>	<b>Pages</b>	<b>Description of change</b>

**History of SOP Implementation**

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**Approval of Site SOP**

	<b>Signature</b>	<b>Date</b> dd/mm/yyyy

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### 1. Policy

Within the framework of the principles inherent in Good Clinical Practice (GCP) of the International Conference on Harmonisation (ICH) and published by Health Canada, this standardized operating procedure (SOP) describes how a case report form (CFR) should be completed and how corrections or modifications should be made to the CRF, whether paper or electronic.

This SOP concerns all institutional personnel working in clinical research on studies involving human subjects and should be adhered to by all those authorized to complete and sign CRFs and to correct or modify data entered onto CRFs.

### 2. Objectives

One of the objectives of this standard procedure is to define the process of collection of clinical data required by the protocol in order to ensure the integrity of said data recorded on a CRF, paper or electronic. Data recorded on a CRF can be generated from source data or documents, or can be directly collected in the CRF in accordance with the protocol.

The other objective of this SOP is to ensure the legibility, authenticity and accuracy of all recorded clinical data collected in a paper or electronic CRF, in accordance with the principles of the ICH.

### 3. Site Responsibilities

#### 3.1 The Research Centre Director or his delegate is responsible for:

- 3.1.1 Approving or updating site SOPs that will be used in the institution according to internal institutional validation procedures;
- 3.1.2 Informing members of the Ethics Committee that this site SOP will be implemented within the institution;
- 3.1.3 Implementing and managing this site SOP within the institution;

#### 3.2 The Sponsor-Investigator or Investigator/Qualified Investigator is responsible for:

- 3.2.1 Ensuring that, during the clinical study, the research team, which will be under his/her supervision will comply with this site SOP.

#### 3.3 Under the supervision of the Research Centre Director or his delegate, the person responsible for site SOPs should:

- 3.3.1 At the time of implementation of each SOP, ensure that clinical study personnel at the institution are trained in procedures and comply with this SOP.
- 3.3.2 In the event that an SOP is modified, provide training for institutional clinical study personnel regarding the change(s) and ensure their compliance with any changes.

### 4. Procedures

#### 4.1 Generalities

The sponsor-investigator or the investigator/qualified investigator should make sure that all clinical study data recorded on a paper or electronic CRF, are accurate, complete and legible.

All the clinical study information should be recorded, handled and stored in a way that allows its accurate reporting, interpretation and verification, ICH 2.10.

#### 4.2 Recording Data on CRFs

4.2.1 Data recorded in the CRF, which are drawn from source data or documents, should correspond to the data appearing in these documents. All variations should be explained, documented and approved by the sponsor-investigator or the investigator/qualified investigator or his delegate.

4.2.2 CRFs should be completed only by authorized persons. This authorization should be documented, as defined in SOP 03.

- 4.2.3 The sponsor-investigator or the investigator/qualified investigator or his delegate should only allow individuals with the required qualifications or training in CRFs completion and data verification to take part in this task. Confirmation of this qualification or training should be completed, as described in SOP 04.
- 4.2.4 For reasons of security and confidentiality of subjects and their data, only non-ambiguous subject identification codes should be used for identification of all data reported in the CRF for each subject, ICH 5.5.5 and SOP 26.
- 4.2.5 The CRF should be completed as soon as the data are available or during the subject's evaluation or follow-up visit.
- 4.2.6 In the case of a paper CRF, use of a black ball-point pen is recommended, especially if the CRF is made up of several copies with carbon paper.
- 4.2.7 If, for any reason, information required in the CRF cannot be provided, it is recommended that specific codes be defined for the missing data. These codes should be defined at the time the CRFs are designed.
- 4.2.8 Data referred to in the protocol, which are directly recorded on paper or electronic CRFs, should be signed and dated by the investigator/qualified investigator or his delegate.

### 4.3 Modifying CRF Data

- 4.3.1 If data are transformed during processing, it should always be possible to compare the original data and observations with the processed data, ICH 5.5.4.
- 4.3.2 In order to respect this principle, a tracking mechanism for all modifications of the data should be established. This process of control, verification and correction should allow for comparison with the source data, and should make it possible to determine by whom, when and why the modification was made.

#### Paper CRFs

- 4.3.3 If errors are noted and modifications made to the CRF before being sent to entry and data processing personnel, the incorrect data should be crossed out with a single line, so as to remain legible, and the new data written next to the incorrect data. The person who makes the correction should initial and date the change. If applicable, the reason for correction may also be indicated.
- 4.3.4 **The use of corrector fluid or other correction material is not authorized.**
- 4.3.5 Any modifications made to paper CRFs should be justified, reviewed, authorized and approved by the investigator/qualified investigator. To confirm this approval, it is recommended that the investigator/qualified investigator signs and dates the CRF only when the correction process is finished and the CRF is ready to be transmitted to personnel responsible for capture and processing of the data, designated by the sponsor/sponsor-investigator.

4.3.6 In the case where correction to the data is made after the CRF is retrieved from the site, any necessary data modification requires completion of the data clarification form (DCF), as described in SOP 24. The original DCF is retained by the sponsor/sponsor-investigator and one copy given to the investigator/qualified investigator, ICH 8.3.15.

#### **Electronic CRFs**

4.3.7 Any modification or addition to the information should be made by those delegated by the sponsor-investigator or investigator/qualified investigator and trained in recording and correction of data on electronic CRFs.

4.3.8 Any modification or addition to the information should be confirmed and signed by the sponsor-investigator or investigator/qualified investigator using an electronic signature.

4.3.9 The sponsor-investigator should ensure that the electronic system guarantees tracking and stores all successive modifications in memory, ICH 5.5.4 and FDA Guidance for the Industry Part 11, Electronic Records; Electronic Signatures – Scope and Application.

4.3.10 The sponsor-investigator or the investigator/qualified investigator should maintain a copy of the certified data backup, ICH 5.5.3.f.

4.3.11 If it is stipulated in the protocol that the clinical data are transferred to another system, the transfer should be validated and secure as mentioned in the protocol. This transfer should be documented in the protocol.

#### **4.4 Confirming and Signing CRFs**

4.4.1 Once the CRF is completed, the sponsor-investigator or the investigator/qualified investigator should ensure the integrity and coherence of the collected information.

4.4.2 The CRF should be signed and dated by the sponsor-investigator or the investigator/qualified investigator, as defined by the delegation/signature form. reference SOP 03. This delegation should be retained with the essential study documents, SOP 02.

## 5. References

Health Canada, Guidance for Industry, Good Clinical Practice: Consolidated guideline, ICH Topic E6, 1997. <sup>-3</sup>

Food and Drug Administration (FDA), Electronic Records; Electronic Signatures Final Rule. 21 CFR Part 11, Federal Register Vol. 62, No 54, March 20, 1997. <sup>-1</sup>

Food and Drug Administration (FDA), Guidance for Industry: Computerized systems used in clinical trials, April 1999, <sup>-2</sup>

Ministère de la santé et des services sociaux (MSSS), Cadre Global de Gestion des Actifs Informationnels appartenant aux organismes du réseau de la santé et des services sociaux : Volet Sécurité, septembre 2002. <sup>-1</sup>

SOP-02 Organizing a Site for Clinical Research.

SOP-03 Research Team: Role Definitions, Responsibilities and Task Delegation

SOP-04 Site Research Team: Competence, Knowledge and Training

SOP-24 Clinical Data Management, Paper or Electronic Format

SOP-26 Security and Confidentiality of Data

## APPENDIX 1 INSTRUCTIONS SPECIFIC TO THE SITE (EXAMPLES)

1. **Filing System**
2. **Location of Filing System**
3. **Annual Approval or Revision**
4. **Specific Responsibilities of the Institution**
5. **Procedures**
6. **References**
7. **Appendices**