

<b>OFFICE FOR EDUCATION &amp; QUALITY IN CLINICAL RESEARCH</b>	<b>CATEGORY</b>	<b>Clinical Research: Project Activities</b>
	<b>SUBJECT</b>	<b>Case Report Form Completion</b>
	<b>SOP #</b>	<b>4.1</b>
	<b>EFFECTIVE DATE</b>	<b>August 6, 2008</b>
	<b>REVISION DATE</b>	<b>December 15, 2017</b>

**OBJECTIVE**

Describe how to complete Case Report Forms. These procedures apply to all clinical research activities approved by the Office for Human Subjects Research conducted within the Hennepin County Medical Center campus.

**APPLICABLE REGULATIONS AND GUIDELINES**

21 CFR 11                      Electronic Records  
21 CFR 312                    Investigational New Drug Application  
21 CFR 812                    Investigational Device Exemptions

**REFERENCES TO RELATED SOPs**

SOP 2.1  
SOP 2.2  
SOP 2.9  
SOP 2.11  
SOP 2.12

**ATTACHMENTS**

None

- 1) Assure that all personnel writing in the Case Report Form (CRF) have signed the delegation of authority log and that it is placed in the regulatory binder.
- 2) Identify data to be collected from appropriate primary source documentation. Ensure that there is a data source for each CRF entry.
- 3) Transcribe data to the CRF as soon as possible after data has been collected.
- 4) Enter data in black ink (paper CRF) unless otherwise directed.
- 5) Do not leave data points blank. If data does not exist, use required sponsor categorization (i.e., ND = not done, NA = not applicable) or single horizontal slash mark if so directed.
- 6) Do not add any extraneous data to a CRF.
- 7) To amend data in a paper CRF:
  - a) Cross out erroneous entry with a single line
  - b) Write correct entry alongside
  - c) Initial change
  - d) Date change
  - e) Never erase
  - f) Never use white-out

- g) Never write over an entry
- 8) Ensure that staff is appropriately trained according to sponsor specifications when using electronic data capture.