

# The Clinical Research Center Research Practice Manual



## Guidelines for Research Data Collection – RPG-07

### Guideline

#### Purpose

The purpose of the Data Collection Guideline is to provide investigators and study staff with CRC recommendations for ensuring the collection of high quality data in clinical research studies.

#### Definitions

**Case Report Form (CRF)** – 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. (ICH GCP 1.11)

**Electronic Data Capture (EDC) System** - a computerized database designed for the collection of clinical data

**Manual of Operations (MOO)** – a document that describes in detail the science, methods and procedures for implementation of a clinical research study.

**Source Data** – information contained within source documents that represent the original documentation of findings and observations of subjects participating in clinical research studies. (ICH GCP 1.51)

**Source Documents** – original documents, data and records such as medical records, laboratory results, x-rays, pharmacy records and patient diaries. (ICH GCP 1.52)

**QxQ** – question-by-question instruction guide on how to complete a Case Report Form (CRF)

### Procedure

#### **Data Collection along the Research Study Continuum:**

Data collection encompasses a wide range of information gathered for a study and may occur at many time points throughout the research study. Collecting data usually begins at pre-screening or recruitment and continues through study termination. Throughout each step of data collection, ensure that the data captured is de-identified, accurate, relevant, and free from bias. Complete and accurate data collection will result in fewer queries to resolve and more meaningful data

analysis.

## **GENERAL GUIDELINES FOR DATA COLLECTION:**

### **Before beginning data collection**

- Familiarize yourself with the following documents/tools:
  - ❖ **CRFs** (Know which fields are required and understand the flow of the CRF using the skip logic provided.)
  - ❖ **Source documents** (Know where the source data comes from.)
  - ❖ **Data collection instructions** in the MOO
  - ❖ **Other data collection tools** (i.e., Training Manuals, QxQ)
- Have training sessions on how to collect data on CRFs and EDC systems

*Note: Only trained and authorized staff should complete data collection.*

### **During data collection**

- Use assigned Study ID numbers on all forms. Do NOT record patient identifiers on CRFs (i.e., Name, Medical Record Number [MRN], Social Security Number [SSN]).
- Record the Study ID on every page of the CRF. This helps prevent loss of data if the pages of the CRF are separated.
- Collect data during the participant's study visit or as soon as it is available (i.e., lab results from electronic medical records).
- Follow all case report form instructions carefully.
- Use only the most currently approved version of CRFs.
- All forms should be completed in black ballpoint pen unless otherwise specified (i.e., No.2 pencil for fill-in-the-bubble questionnaires). Felt-tip pens and markers should be avoided as the ink can bleed into paper or can run if it touches water.
- Record data in free-text fields clearly and legibly. Ensure the spelling is correct.
- Use only study-approved abbreviations to avoid serious clinical and research errors.
- For numeric data fields, record data to the specified number of decimal places. Use leading and trailing zeros when indicated.
- When errors occur, draw a single line through the incorrect entry and write the correct entry above or near the original entry. Initial and date the change. Do not scratch-out the incorrect entry or use correction fluid or tape to fix errors. It is important not to obscure the original entry.
- Only capture data in the specified fields of the CRF. Avoid writing elaborative notes in the margin. If elaboration of a response is necessary, defer to the study PI to interpret the note and record appropriately.
- Obtain PI signatures, if specified on the CRF.
- If data for a field is unavailable, unknown, or not applicable, use an acceptable notation to account for the missing data. The CRC uses the following codes to indicate different instances of missing data:

| Code | Description        |
|------|--------------------|
| -3   | Not Applicable     |
| -5   | Not Done / Refused |
| -8   | Unknown            |
| -9   | Missing            |

### **Immediately following data collection**

- Review CRFs for completeness and accuracy immediately following data collection. If data are incomplete, try to obtain the information before the subject leaves the study visit.
- If using an EDC system, enter the data captured on CRFs within 3 days of collection.
- Follow study quality assurance procedures as documented in the study Manual of Operations.
- Keep CRFs in the appropriate study folders in a locked drawer or cabinet. Source documents should be stored separately from the CRFs.

**Other Information:** The ALCOA principle for source documents – Accurate, Legible, Contemporaneous, Original, Attributable, Complete, Consistent, Enduring and Available is a Good Clinical Practice. Here is a link for examples and a easy-to-read summary on Good Documentation Practice in Clinical Research:

<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3121265/>

## References

- Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance. April 1996. ICH. 4 March 2009  
<<http://www.fda.gov/cder/guidance/959fnl.pdf>>
- Woolen, SW. The Facts about Source Documents. June 29, 1999. DIA Meeting. 4 March 2009  
<<http://www.fda.gov/cder/present/dia-699/wollen-dia99/wollen-dia99.ppt>>
- The Society for Clinical Data Management. “CRF Completion Guidelines” June 2008. Good Clinical Data Management Practices. 4 March 2009 <<http://www.scdm.org/gcdmp/>>
- Kolman J, Meng P, Scott G. “Case Report Form (CRF) Completion” Good Clinical Practice. John Wiley and Sons, Ltd. 1998.
- Fonds de la recherche en santé du Québec “How to Fill in a Case Report Form (CRF) and Modify Data” 2006. Standard Operating Procedures to Ensure Good Clinical Practice at Clinical Research Sites. 4 March 2009. <<http://www.frsq.gouv.qc.ca/en/financement/SOP.shtml>>

## Document Attributes

|                                 |   |  |              |
|---------------------------------|---|--|--------------|
| <b>Title</b>                    | Guidelines for Research Data Collection – RPG-07  |  |              |
| <b>Author</b>                   | Sarah Krathwohl   | <b>Date of Origin</b>  | October 2010 |
| <b>Reviewed/<br/>Revised by</b> | Kim Chin  | <b>Dates<br/>Reviewed/Revised</b>  | 08/28/13     |
| <b>Copyright</b>                | ©Boston Children’s Hospital, 2013   | <b>Last Modified</b>   | 08/28/2013   |
| <b>Approved</b>                 | <b><u>SIGNATURE ON FILE</u></b><br>Stavroula Osganian, MD, ScD, MPH<br>Co-Chief, Clinical Research Center | <b><u>SIGNATURE ON FILE</u></b><br>Ellis Neufeld, MD, PhD<br>Associate Chief, Division of<br>Hematology/Oncology |              |

**Acknowledgement:** The following CHB staff made substantive contributions to the development of this Guideline: Sarah Krathwohl, Handan Titiz, Tracy A. Antonelli.

**Disclaimer:** Should Hospital and CRC policies conflict, Hospital policy will supersede CRC policy in all cases.