

Title: Data Management	*Applicable to: Beaumont Health	Effective Date: 01/11/2018
Policy Owner: Administrative Director	Document Type: Policy	Last Periodic Review Date: 01/11/2018 Functional Area: Clinical Research SOP's, Research Institute

***For This Document, Beaumont Health Includes:**

- Beaumont Corporate Shared Services
- Beaumont Hospital, Dearborn
- Beaumont Hospital, Farmington Hills
- Beaumont Hospital, Grosse Pointe
- Beaumont Hospital, Royal Oak
- Beaumont Hospital, Taylor
- Beaumont Hospital, Trenton
- Beaumont Hospital, Troy
- Beaumont Hospital, Wayne
- Beaumont Medical Group
- Beaumont Pharmacy Solutions
- Post Acute Care

I. PURPOSE:

This standard operating procedure (SOP) describes the processes followed for the collection of clinical research data, transcription of the data to case report forms (CRFs), and the management of the data.

II. BACKGROUND:

Research data refers to information collected, stored and processed in a systematized manner to meet the objectives and endpoints of a particular research study. Key research personnel must manage data responsibly and in compliance with regulations, for the purpose of delivering the highest quality data and maximizing the impact of the study. Efficient and accurate data management is critical to data integrity.

III. SCOPE:

This SOP applies to data management for all clinical studies at Beaumont Health.

IV. RESPONSIBILITY:

This SOP applies to key research personnel involved in data collection, transcription to CRFs, and the management of the data.

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V. PROCEDURES:

A. Collection of clinical research data

1. Ensure copies of the most recent Institutional Review Board (IRB)-approved Informed Consent and Authorization Document are available for participant enrollment.
2. Ensure all data entered on the CRF is substantiated and verifiable by appropriate source documentation.
3. Develop systematic methods for tracking data. Such methods may include checklists or logs.

B. Transcription of data to case report forms, including remote data entry

1. Complete all fields on the case report forms (CRF's) according to sponsor specifications.
2. Paper CRFs
 - a. Record all documentation in black ballpoint pen.
 - b. Correct an error by striking through the error, dating and initialing it, and making the correction. Ensure the original entry is not obliterated.
 - c. Ensure data for CRFs are transcribed promptly and accurately from the source documentation. Institute quality assurance measures, such as "double checking" entries, to maximize efficiency and eliminate unnecessary data clarifications.
3. If the sponsor requires remote data entry, ensure that data is entered promptly and accurately from the source documentation, according to sponsor specifications.
4. As required by the protocol, remove patient identifiers from the source document copies and the CRF. Label these documents with the subject identification code, as defined by the sponsor.

C. Management of the data

1. Assure that a second research staff member reviews the first subject's completed CRFs for completeness and accuracy.
2. Request that the monitor review the first enrolled participant's CRF for accuracy and completeness soon after enrollment.
3. Request a copy of the sponsor's SOPs for making changes or corrections to the CRFs.
4. Review and correct any discrepancies noted at the sponsor's monitoring visit and record on the monitoring correction form (also called a monitoring report or trip report). If a sponsor-specific form or report is not available, assure that discrepancies are noted on a generic monitoring correction form to assure a trail of clarifications and corrections.
5. Assure the monitoring correction forms are kept in the regulatory files for the study.
6. Correct errors to the CRFs noted at the monitoring visit by using the procedures described above.

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7. Be knowledgeable about the sponsor’s procedures related to data clarification requests, such as distribution methodology and expected response timelines. Respond to data clarification requests per sponsor directions.
8. At the conclusion of the study, ensure that data is retained according to regulatory requirements, sponsor requirements, and in accordance with [Research Record Retention and Destruction](#) Institutional Review Board Policy.

VI. APPLICABLE REGULATIONS AND GUIDELINES:

21 CFR 312.50 General responsibilities of sponsors
 21 CFR 312.56 Review of ongoing investigations
 21 CFR 312.60 General responsibilities of investigators
 21 CFR 312.62 Investigator recordkeeping and record retention
 21 CFR 312.64 Investigator reports
 21 CFR 312.68 Inspection of investigator's records and reports
 21 CFR 312.70 Disqualification of a clinical investigator
 FDA Information Sheets, October 1995 Recordkeeping in Clinical Investigations
 Guidelines for the Monitoring of Clinical Investigations, January 1988
 International Conference on Harmonization; Good Clinical Practice: Consolidated Guideline, May 1997

VII. REFERENCES TO OTHER APPLICABLE SOP:

Research Administration Policy [Responsibilities of the Principal Investigator](#)
 Clinical Research Policy [Responsibilities of the Research Team](#)
 Clinical Research Policy [Site-Sponsor/Contract Research Organization \(CRO\) Communications](#)
 Clinical Research Policy [Regulatory Files and Study Subject Records](#)
 Clinical Research Policy [External Regulatory Body Inspections or Audits](#)

CORPORATE AUTHORITY:

Beaumont Health (“BH”) as the corporate parent to William Beaumont Hospital, Botsford General Hospital, and Oakwood Healthcare Inc., (“Subsidiary Hospitals”) establishes the standards for all policies related to the clinical, administrative and financial operations of the Subsidiary Hospitals. The Subsidiary Hospitals, which hold all health facility and agency licenses according to Michigan law, are the covered entities and the providers of health care services under the corporate direction of BH. The Subsidiary Hospitals’ workforces are collectively designated as BH workforce throughout BH policies.