Title: **Sponsor/Contract Research Organization (CRO) Monitoring Visits**	*Applicable to: **Beaumont Health**	Effective Date: **01/11/2018** Last Periodic Review Date: **01/11/2018**
Policy Owner: **Administrative Director**	Document Type: **Policy**	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 procedures followed by key research personnel engaged in clinical research at Beaumont Health during a periodic monitoring visit from the sponsor representative.

II. SCOPE:

This SOP describes the steps followed from the time the monitoring visit is scheduled until all follow-up activities associated with the visit have been completed.

III. RESPONSIBILITY:

This SOP applies to principal investigators (PI) and key research personnel involved in arranging, managing, participating in, and/or resolving any outstanding items resulting from the monitoring visit.

IV. PROCEDURES:

A. **Preparing for the monitoring visit**

1. The primary key research personnel assigned to the study (e.g., Research Nurse Clinician, Clinical Research Coordinator, etc.) will schedule all monitor visits, including the first visit

following initial enrollment or periodic visits throughout the study. When possible, the next monitor visit should be scheduled at the conclusion of the current visit.

2. Request the monitor's agenda, if not already provided in a monitor visit letter, to ensure appropriate key research personnel will be available as needed (e.g., PI, study pharmacist).
3. Ensure all regulatory documentation and case report forms (CRFs) are complete and available for review.
4. Ensure all unanticipated problems and protocol deviations have been reported to the Institutional Review Board (IRB) consistent with IRB policy.
5. Ensure all unanticipated problems, protocol deviations and adverse events are reported to the sponsor consistent with the protocol and IRB policy.
6. Ensure all data queries received to date have been resolved to the extent possible.
7. Assure the test article is securely stored according to the instructions in the protocol (e.g., temperature or light specifications) and all accountability records are updated.
8. Ensure the appropriate study participant medical records will be available for review at the time of the monitoring visit. The monitor or any other sponsor representative(s) is not allowed to navigate the electronic health record (EHR) using an employee's login information. The research employee can either print the applicable source data directly from EHR, or navigate through the system while the monitor observes and verifies source. Alternately, sponsor monitor access to EHR can be requested in advance by contacting the RI Compliance Coordinator with the monitor's first and last name, birthdate, zip code and last four digits of their social security number (or a four digit PIN if they prefer). The Compliance Coordinator provides this information to Information Technology and notifies the monitor of their user identification information. The Clinical Research Manager is able to set up records release for specific studies.
9. Be prepared to ask questions or discuss any concerns you may have about communications or operations of the study.
10. Ensure data entered on CRFs or queries is accurate, complete, legible and timely.
11. Ensure all data can be verified with an original source document. Data on CRFs must be consistent with the source documents, or discrepancies should be explained. Maintain source documentation with study files.
12. Ensure key personnel who collect or enter data sign and date the data, so it is attributable. Any changes or corrections must be made by key personnel. Any change or correction should include an audit trail, clearly indicating who made the change, when and for what reason.
13. Do not accept or use a stamped signature for the PI or other key personnel.

B. **Managing the monitoring visit**

1. Provide monitors a designated workstation, and directions to areas of permitted access while onsite i.e., public lobby areas and restroom. Monitors may not visit clinical or administrative areas without a valid study related purpose. Personally escort monitors to any required areas.
2. Instruct monitors all information requests during their visit must flow through the research coordinator or clinical research manager. This includes regulatory and patient binders/CRFs, source documents, access to electronic medical records, etc.
3. Instruct monitors use of computers, copy machines, fax machines, clinical equipment, etc., is solely for accessing participant electronic medical records, previously assigned to them. Monitors may not bring copy or scanning devices into any Beaumont facility. Monitors may not take photos or scan Beaumont research data or documents without written permission of the clinical research manager.
4. Ensure the monitor signs the monitoring visit log.
5. Assure the study monitor has all documents required to complete the monitoring visit.
6. Provide monitor with an update on any study-related issues.
7. Throughout the visit, check periodically with the monitor and provide information or documents as needed.
8. At visit conclusion, the monitor will identify any outstanding items requiring attention. Items may be related to:
   a. Protocol adherence
   b. Regulatory submissions or documentation
   c. Source document verification
   d. Test article storage, distribution, and accountability or
   e. Requirements for data storage.

1. The research coordinator managing the monitor visit will address any outstanding items and may refer the monitor to the clinical research manager as needed (e.g., payment issues, etc.).
2. The monitor may request to speak with the PI, pharmacist, or other key personnel who should be available during the visit.
3. Ensure only key personnel to whom the PI has formally delegated CRF completion/ corrections or query response completes these activities.
4. Do not permit sponsor representatives, such as monitors, to generate or record data. This includes prohibiting them from completing source documents or writing on CRFs/data queries.

9. Follow-up after the monitoring visit

1. Action required subsequent to a monitoring visit is to be provided in writing to the PI and clinical research manager in the form of a monitor visit summary.

2. Ensure any outstanding items are addressed in a timely manner and the necessary information is provided to the sponsor and/or monitor.
3. Provide outstanding item resolution to the sponsor and/or monitor and document resolution in the study files (e.g., fax additional source documentation for an adverse event to the sponsor and/or monitor and file the fax with confirmation, in the AE section of the regulatory binder(s)).
4. File the monitor visit letter in the regulatory binder.

V. REFERENCES:

21 CFR 312.50 General Responsibilities of Sponsors
21 CFR 312.56 Review of Ongoing Investigations
21 CFR 312.59 Disposition of Unused Supply of Investigational Drug
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 312.66 Assurance of IRB Review
21 CFR 312.68 Inspection of Investigator's Records and Reports
September 1993 FDA Compliance Program Guidance Manual 7348.811: Clinical Investigators
September 1994 FDA Compliance Program Guidance Manual 7348.810: Sponsors, Contract Research Organizations and Monitors
January 1988 Guidelines for the Monitoring of Clinical Investigations
May 1997 International Conference on Harmonization (ICH) Good Clinical Practices

VI. ASSOCIATED POLICIES AND SOPs:

Clinical Research Policy *Reporting an Unanticipated Problem Involving Risk to Participants or Others*
Clinical Research Policy *Protocol Deviations*
Clinical Research SOP *Responsibilities of the Research Team*
Clinical Research SOP *Site Initiation Visit*
Clinical Research SOP *Site-Sponsor/Contract Research Organization (CRO) Communications*
Clinical Research SOP *Regulatory Files and Study Subject Records*
Clinical Research SOP 611 *Study Close-Out Visit*
Clinical Research SOP 607 *Test Article Accountability, Storage, Distribution and Return* Clinical Research SOP 614 *Data Management*

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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.