

Title: Site Initiation Visit	*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 when the study sponsor conducts a site initiation visit to:

- A. Prepare site personnel to implement the protocol according to Good Clinical Practice (GCP) requirements.
- B. Review test article administration and accountability.
- C. Review instruction on any specialized procedures such as diagnostic tests and electronic data capture systems.
- D. Provide direction for case report form (CRF) completion.

II. SCOPE:

This SOP applies to all clinical studies conducted at Beaumont Health (Beaumont). It describes the steps followed from the time a study initiation visit is scheduled by a sponsor, until all activities associated with the visit have been completed.

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III. RESPONSIBILITY:

This SOP applies to principal investigators (PIs) and other key research personnel involved in managing or participating in the site initiation visit or study communications.

IV. PROCEDURES:

A. Preparing for the site initiation visit:

1. Coordinate the site initiation visit schedule to assure PI availability.
2. Identify other key research or clinical personnel likely to be involved in conducting the study.
3. If needed, schedule time throughout the visit to review study materials with support staff from clinical departments involved in the study (e.g., Emergency Department, Cath Lab, Imaging, etc.).
4. If needed, schedule educational session(s) with involved clinical staff (e.g., residents, fellows, or referring physicians).
5. Assign study to appropriate clinical research personnel. Assure personnel are familiar with sponsor-provided study materials (e.g., Protocol, Operations Manual, CRFs) prior to the initiation visit.
6. Assure appropriate key research personnel assigned to the study are available to attend the initiation visit.
7. If requested by the sponsor representative, provide directions and assistance in identifying nearby accommodations.
8. Ensure a final budget and contract is in process, if not fully executed.
9. Review study regulatory files for completeness.
10. Establish the receipt of adequate test article supplies (if applicable) or ensure the location of test article storage is ready for review and meets the sponsor's requirements.
11. Identify any sponsor-provided supplies needed once enrollment begins (e.g., paper-based CRFs, lab draw and shipping supplies).
12. Ensure any study-specific initiation visit checklists are completed in advance of the visit.
13. Ensure Institutional Review Board (IRB) approval has been obtained or review is in process.

B. Conducting the site initiation visit:

1. Assure the PI is present for the introductory meeting.
2. Review with the sponsor representative:
 - a. Details of the protocol, including study operations. Discussion should include which key personnel are authorized to perform study-related functions or procedures (e.g., only MD/DO can perform study history and physical exams). Document operational questions not covered in the protocol and the answers provided by the sponsor.

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- b. Test article administration and accountability (if applicable).
 - c. Instruction on study-specific activities such as diagnostic tests, lab kits or study-required software and any related record-keeping requirements (e.g., temperature logs, calibration logs, etc.).
 - d. Directions for source documentation and/or CRF completion.
 - e. Assure CRF format meets minimum CRF standards, as described in Clinical Research SOP, [Pre-Study Site Selection Visit](#).
 - f. Required source documents and documentation to be provided at future monitoring visits.
 - g. Any applicable study-specific training involving protocol execution (e.g., surgical skills in-service for physician-investigators).
3. Provide the sponsor representative with an update on any study-related issues.
 4. Identify important sponsor and/or monitoring body contacts and corresponding timeframes (e.g., enrollment logs safety reporting).

C. Following up after the site initiation visit:

1. File all training certificates in the regulatory binder. If the sponsor does not provide a record of training, record the timing and details of any training sessions and file in the regulatory binder.
2. Ensure receipt of sponsor/CRO written documentation summarizing important agreements made during the visit.
3. Assemble screening/enrollment materials.
4. Activate recruitment plan once IRB approval is obtained.

V. REFERENCE:

- 21 CFR 312.50 General responsibilities of sponsors
- 21 CFR 312.52 Transfer of obligations to a contract research organization
- 21 CFR 312.60 General responsibilities of investigators
- 21 CFR 312.66 Assurance of IRB review
- 21 CFR 312.68 Inspection of investigator's records and reports
- January 1988 Guidelines for the Monitoring of Clinical Investigations

VI. ASSOCIATED SOPs:

- [Responsibilities of the Research Team](#) Clinical Research SOP
- [Pre-Study Site Selection Visit](#) Clinical Research SOP
- [Site-Sponsor/Contract Research Organization \(CRO\) Communications](#) Clinical Research SOP
- [Regulatory Files and Study Subject Records](#) Clinical Research SOP
- RI Policy [Responsibilities of the Principal Investigator](#)

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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.