

Title: Pre-Study Site Selection Visit	*Applicable to: Beaumont Health	Effective Date: 01/12/2018
Policy Owner: Administrative Director	Document Type: Policy	Last Periodic Review Date: 01/12/2018 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 a research sponsor wishes to conduct a pre-study site visit at Beaumont Health. The purpose of a pre-study visit is for the study sponsor to assess whether or not Beaumont will be an adequate site, including evaluation of the facilities, investigator(s) and study staff qualifications and experience, and the potential clinical population from which subjects will be recruited and enrolled.

II. SCOPE:

This SOP describes the steps to be followed from the time a pre-study site visit is scheduled with a sponsor, until all follow-up activities associated with the visit have been completed.

III. RESPONSIBILITY:

This SOP applies to investigators, other key research personnel and support staff involved in arranging, managing, or participating in the pre-study site visit. This SOP applies to those in clinical research departments within the Research Institute, as well as those involved in clinical research outside of an established clinical research department.

IV. PROCEDURES:

A. Preparing for the pre-study visit:

1. Ensure the sponsor's Confidentiality Disclosure Agreement (CDA) has been forwarded to Research Administration, in accordance with Research Administration Policy 107 *Processing*

Disclaimer: User must ensure that any printed copies of this policy/procedure are current by checking the online version of the policy/procedure before use.

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- Confidentiality Disclosure Agreements*, and signed by Research Administration, the principal investigator (when requested) and the sponsor.
2. Identify key research personnel likely to be involved in conducting the study under consideration.
 3. Identify which Institutional Review Board (IRB) (Beaumont or an approved external IRB) will oversee the study.
 4. Gather critical study documents, if provided by the sponsor:
 - a. Protocol
 - b. Investigator Brochure
 - c. Case Report Forms (CRFs)
 - d. Budget worksheet
 - e. Draft contract
 - f. Sponsor Financial Disclosure.
 5. Discuss Beaumont’s minimum CRF requirements for sponsored research with sponsor. Sponsors must provide:
 - a. Written CRF completion instructions/guidelines.
 - b. CRF training, at study outset and with each CRF revision, appropriate to the scope of document changes.
 - c. CRF revisions-CRFs must be consistently versioned and a table of changes provided.
 - d. Paper CRFs must be NCR triplicate. Single copy CRFs requiring staff to make photocopies and send to the sponsor are unacceptable.
 - e. Standardized data query process with an adequate audit trail. Sponsor must provide systems to ensure CRFs at the site, including data changes, match CRFs maintained by the sponsor. Data changes should be signed by both the research staff member and the principal investigator.
 - f. Initial CRF entries, data changes on CRFs, and queries must be attributable to the individual generating them, consistent with Good Clinical Practices (GCPs). For paper CRFs, signature and dates are required. Stamped signatures are prohibited.
 - g. Electronic CRFs with validations for FDA regulated research. Review the protocol and other study-related materials to assess the feasibility of conducting the study at this site. Provide necessary information, as requested by the research manager, so the study can undergo review by the Protocol Review Committee, and when applicable, the Scientific Review Committee.
 6. Determine if the sponsor has any areas of special interest which require advance scheduling, such as:
 - a. Visiting the treatment site (clinic or hospital), pharmacy, laboratory, medical records department
 - b. Viewing any specialized equipment needed to implement the study

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- c. Meeting with ancillary personnel involved in any specialized data collection
 - d. Visiting any ancillary facilities.
 - 7. If not on file, obtain copies of current curriculum vitae and licensures from key research personnel. These documents should be updated and signed within the preceding two years (or more frequently if required by the sponsor). Provide originals/photocopies to the sponsor if required.
 - 8. Set an agreeable meeting date with the study sponsor representative, principal investigator, and other important key research personnel who may be involved in the conduct of the study.
 - 9. Prepare the following information, as requested by the sponsor:
 - a. Contact information for key individuals e.g., administrative contacts for contract and budget negotiation, the clinical department regulatory coordinator, research coordinator or research nurse clinician.
 - b. If Beaumont IRB will be the IRB of record, provide dates of future IRB meetings, IRB rosters and overview of the protocol review process.
 - 10. Ensure advance permission from the appropriate Beaumont leader to allow sponsor representatives to tour restricted Beaumont areas.
- B. Conducting the pre-study site visit:**
- 1. Meet with sponsor/clinical research organization (CRO) representative(s) to:
 - a. Review the protocol:
 - Inclusion and exclusion criteria
 - Patient visit schedule
 - Provisions for specialized procedures
 - Laboratory, central or local
 - Data entry, electronic or paper CRFs
 - Storage space required for study article, specialized equipment, computers etc.
 - b. Review the Investigator’s Brochure
 - c. Identify the appropriate paths of communication between the sponsor/CRO and Beaumont clinical site.
 - 2. Tour the areas where the clinical trial will be conducted:
 - a. Exam rooms
 - b. Laboratory area
 - c. Storage area for supplies and/or test article
 - d. Pharmacy
 - e. Hospital and/or clinical area
 - f. Clinical research department
 - g. Any special testing areas.

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3. Request from the sponsor the anticipated study timeline including key dates (e.g., investigators' meeting, study initiation meeting, date of test article availability, date for potential start of recruitment and enrollment).
4. Establish contractual process and obtain draft contract if not already received.

C. Following the pre-study site visit:

1. Request written notification from the sponsor if site selection is confirmed.
2. Once the final protocol is obtained, prepare the IRB submission and submit to the IRB for review.
3. Forward the clinical trial agreement and budget to Research Administration and Finance.
4. Plan for site initiation meeting.

V. REFERENCES:

- 21 CFR 312.50 General responsibilities of sponsors
- 21 CFR 312.53 Selecting investigators and monitors
- 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:

- 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 [*Regulatory Files and Study Subject Records*](#)
- Research Administration [*Protocol Review Committee Process*](#)

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.