

Title: Site-Sponsor/Contract Research Organization (CRO) Communications	*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 communication between key research personnel and the sponsor/contract research organization (CRO), including telephone and written interactions, during the course of a clinical research study conducted at Beaumont Health (BH).

II. SCOPE:

This SOP applies to communications between BH personnel involved in the conduct of clinical research and sponsors/CROs. These communications serve to protect the safety and well-being of participants by assuring that studies are conducted compliantly, sponsors/CROs are fully appraised of study site activities, and key research personnel are informed of new information about the study provided by the sponsor.

III. RESPONSIBILITY:

This SOP applies to key research personnel involved in the conduct of clinical trials at BH.

IV. PROCEDURES:

A. General communications

1. Provide the sponsor/CRO a contact list of BH personnel involved in study start up, along with each individual's role (e.g., clinical research manager (CRM) will be involved in

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confidentiality disclosure agreement (CDA), contract and budget negotiations; regulatory coordinator will handle the Institutional Review Board (IRB) submission; research nurse clinician or research coordinator will be responsible for operational start up).

2. Communicate regularly, courteously and in accordance with Beaumont standards, with the sponsor/CRO about all study-related issues.
3. Be familiar with the sponsor's SOPs pertaining to communications, including reporting timelines and preferred communication mode.
4. Keep originals or photocopies of all study-related communications, including faxes with corresponding confirmations, e-mails, and written summaries of phone conversations. File all communication documents in the appropriate section of the regulatory binder.
5. Retain all sponsor-generated communications regarding conduct of the study (e.g., teleconference announcement) in the correspondence section of the regulatory binder. Budget, payment, financial disclosure forms, and other contractual or financial communications should be filed separately from the regulatory binder. Ensure information is communicated to the principal investigator (PI) and other key research personnel as applicable.
6. Bring concerns about sponsor communication or other issues related to sponsor conduct to the immediate attention of the PI and CRM.

B. Pre-study communications

1. The PI/CRM is responsible for sending the Confidentiality Disclosure Agreement to Research Administration for review. Once reviewed and signed by Research Administration, it is returned to the sponsor and clinical research department.
2. Notify the sponsor/CRO of the PI's decision to conduct the research study at BH.
3. Send the signed protocol signature page (if appropriate) to the sponsor/CRO.
4. Submit all pre-study regulatory documents to the IRB.
5. Send updated/revised documents as required by the IRB.
6. Review the protocol and submit any questions concerning interpretation of the protocol or conduct of the study to the sponsor/CRO in writing and file the reply in the regulatory binder. Bring concerns to the attention of the PI and CRM.

C. Communications while the study is ongoing

1. Submit screening and/or enrollment logs to the sponsor/CRO by the preferred mode of communication.
2. Notify sponsor/CRO about onsite Unanticipated Problems (UPs), and serious adverse events (SAEs), per the sponsor's definitions and timelines, as defined in the protocol, sponsor Operations Manual, or IRB policies. Receive offsite safety reports from the sponsor and provide to the PI; report those which the sponsor determines are UPs to the IRB.

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3. Communicate protocol deviations to the IRB of record, in accordance with IRB policies. Report to the sponsor in accordance with the protocol or other written instructions, except when the sponsor has either not provided instruction, or when the sponsor reporting criteria is less stringent than the minimum reporting requirements described in the IRB policy. In such cases, adhere to the minimum reporting criteria described in the policy. Submit completed case report forms (paper-based or electronic data capture) to the sponsor/CRO in accordance with the clinical trial agreement.
4. Respond promptly to data queries as requested via fax, e-mail, and/or direct electronic data capture resolution, per the sponsor’s requirements.
5. Communicate significant regulatory changes per the sponsor’s requirements (e.g., IRB response letter of an unanticipated problem or protocol deviation report, IRB approval of a revised consent document, etc.). Submit sponsor-generated protocol amendments to the IRB of record, per IRB policy. Once approval is obtained, in-service the pertinent research personnel or involved clinical staff regarding the changes prior to implementation. Maintain training records in the regulatory binder.

The PI reviews safety reports received from the sponsor (e.g., off-site events), reporting to the IRB those off-site events which the sponsor determines constitute UPs. Notification of other key research personnel and/or enrolled participants may be necessary (e.g., new risk identified related to investigational treatment).

D. Communications after the study is completed

1. Provide the sponsor/CRO with any required regulatory correspondence related to study close-out (e.g., IRB Final Report/Closure letter).
2. Ensure all close-out activities are performed (e.g., monitor close-out visit) and any sponsor/CRO requirements are met. File all close-out communications in the appropriate section of the regulatory binder (e.g., documents related to return or disposal of test article or lab supplies).
3. Inform sponsor/CRO and Research Administration promptly if notified by an external regulatory body, such as the Food and Drug Administration (FDA), of an impending inspection, consistent with Clinical Research SOP 601 *External Regulatory Body Inspections or Audits*.

V. REFERENCES:

- 21 CFR 312.32 IND safety reports
- 21 CFR 312.33 Annual reports
- 21 CFR 312.44 Termination
- 21 CFR 50 Protection of Human Subjects

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21 CFR 56 Institutional Review Boards
 FDA Information Sheet, October 1998: Sponsor-Investigator-IRB Interrelationship
 May 1997 International Conference on Harmonization (ICH) Good Clinical Practices

VI. ASSOCIATED POLICIES AND SOPs:

- IRB Policy [*Amendment Requests to the IRB Approved Studies*](#)
- IRB Policy [*Protocol Deviations*](#)
- Clinical Research SOP [*Responsibilities of the Research Team*](#)
- Clinical Research SOP [*Pre-Study Site Selection Visit*](#)
- Clinical Research SOP [*Site Initiation Visit*](#)
- Clinical Research SOP *606 Interactions with the Institutional Review Board*
- Clinical Research SOP [*Regulatory Files and Study Subject Records*](#)
- Clinical Research SOP [*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.