

Title: Study Close Out Visit	*Applicable to: Beaumont Health	Effective Date: 04/04/2018
Policy Owner: Administrative Director	Document Type: Policy	Last Periodic Review Date: 04/04/2018 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 procedures followed by key research personnel engaged in clinical research at Beaumont Health (BH) during a close-out visit with a sponsor representative.

II. SCOPE:

This SOP describes the steps followed from the time the monitor schedules the study close-out visit until all follow-up activities associated with the visit have been completed.

III. RESPONSIBILITY:

This SOP applies to key research personnel involved in arranging, managing, participating in, and/or resolving outstanding items resulting from the study close-out visit.

IV. PROCEDURES:

A. Preparing for the study close-out visit

1. After the last patient has completed all scheduled visits associated with the study, arrange a mutually convenient date and time with the monitor to conduct the study close-out visit.
2. Request the monitor's visit agenda so key research personnel such as pharmacists and/or the Principal Investigator (PI) will be available, as appropriate.

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3. Ensure all regulatory documentation and case report forms (CRFs) not previously monitored are complete and available for review.
4. Ensure all data queries received to date have been resolved.
5. Inventory test article supply and complete final accountability records. If previously instructed to return or destroy test article, assure all required documentation is filed in the appropriate regulatory binder for monitor review. When test article is stored in pharmacy, schedule a meeting with the pharmacist and monitor.
6. Arrange for the monitor to meet with the PI and/or Clinical Research Manager (CRM) to discuss any outstanding issues (e.g., contractual obligations).

B. Managing the study close-out visit

1. Ensure all documentation (e.g., regulatory correspondence) is filed appropriately and ready for the monitor to review during the close-out visit. Discuss all open study-related issues and what steps will be taken to resolve them in order to satisfy the sponsor/CRO requirement(s).
2. Review with the monitor the list of outstanding issues related to regulatory documents, source data verification, test article reconciliation, and any requirements for data retention and storage.
3. Discuss any concerns regarding the possibility of a quality assurance audit and/or inspection by external regulatory bodies. Include the CRM as appropriate.
4. If the study involved electronic data capture, determine when hard copies of all CRFs will be provided to BH.
5. The PI is responsible for ensuring the appropriate follow-up, per the protocol, for any participant experiencing an ongoing unanticipated problem at study end and providing this information to the sponsor, assuring all sponsor's requirements have been met.
6. Arrange for the PI to meet with the monitor to discuss any future considerations (e.g., publication of study data or future studies).

C. Follow-up after the study close-out visit

1. For any remaining test article(s), ensure the item(s) is returned to the sponsor/CRO per their requirements. If the sponsor allows remaining test article to be disposed of at the site following the close-out visit, the authorized key personnel (with verification by a second authorized key personnel) can dispose of the device per sponsor direction or the BH Research Pharmacist can dispose of the drug per sponsor and Investigational Drug Service SOPs. Ensure all documentation is complete (e.g., sponsor drug accountability, destruction logs).
2. In the event the sponsor notifies the PI of any information that could directly affect the health or safety of past or current study subjects or influence the conduct of the study, including but not limited to the study results and information in site monitoring reports and data safety monitoring committee reports as required by the protocol, the investigator and/or the

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- Beaumont Research Institute must report the information to the IRB of record (if not already reported) and, with the IRB, determine what information should be shared with participants.
3. Ensure all test article packing slips and shipment receipts are accounted for and properly filed in the regulatory binder.
 4. Provide the sponsor with any documentation of previously authorized test article disposal and file site copy appropriately. If the randomization code for any test article was broken for any reason, ensure complete documentation has been filed.
 5. Ensure return or destruction of all other study-related materials, such as unused lab kits and CRFs.
 6. Ensure any equipment on loan from the sponsor is returned.
 7. After all data queries have been resolved, check regulatory binders, subject files and other study files for completeness. Arrange for transfer of study documents to secure storage, in accordance with IRB Policy [Research Record Retention and Destruction](#).
 8. Submit the Final Report/Closure Form to the IRB, in accordance with IRB Policy [Study Completion, Closure or Expiration](#). Provide the sponsor/CRO with a copy of the IRB closure letter.
 9. Verify participant stipends have been distributed per the study budget, as outlined in the Informed Consent and Authorization Document.
 10. If the informed consent and authorization document, protocol or contract state participants will be informed of their treatment arm, ascertain from the sponsor how and when this will be completed. Consult with the RI Accountant to assure any associated work by research personnel has been included in the contract and budget.

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
- January 1988 Guidelines for the Monitoring of Clinical Investigations
- May 1997 International Conference on Harmonization (ICH) Good Clinical Practices

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VI. ASSOCIATED POLICIES AND SOPs:

- IRB Policy [Research Record Retention and Destruction](#)
- IRB Policy [Study Completion, Closure or Expiration](#)
- Clinical Research SOP 604, *Investigational and Study Agent Management*
- Clinical Research SOP [Responsibilities of the Research Team](#)
- Clinical Research SOP [Site-Sponsor/Contract Research Organization \(CRO\) Communications](#)
- Clinical Research SOP [Regulatory Files and Study Subject Records](#)
- Clinical Research SOP [Investigational Device Accountability, Storage, Distribution and Return](#)
- Clinical Research SOP [Data Management](#)
- 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.