

Title: <b>Interactions with the Institutional Review Board</b>	*Applicable to: <b>Beaumont Health</b>	Effective Date: <b>01/12/2018</b>
		Last Periodic Review Date: <b>01/12/2018</b>
Policy Owner: <b>Administrative Director</b>	Document Type: <b>Policy</b>	Functional Area: <b>Clinical Research SOP's, Research Institute</b>

**\*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 key research personnel’s essential interactions with the Institutional Review Board (IRB) throughout the research process.

**II. BACKGROUND:**

Effective interactions between the IRB and key research personnel is critical to ethical and sound conduct of clinical research at Beaumont Health (BH). As the BH designated Institutional Review Board, the IRB is responsible for the oversight of all clinical research conducted at Beaumont. The overarching concern of the IRB is the protection of human subjects, which involves safeguarding participant rights, safety and well-being. The IRB assures compliance with applicable federal, regional and institutional policies and procedures governing human participant research by providing initial and continuing review of clinical research studies. It is essential the IRB effectively convey actions, gain clarifications and review study-related information (i.e., unanticipated problem reports or protocol deviation reports) provided by principal investigators (PI).

The PI is responsible for protecting the rights and welfare of participants, and complying with all regulations applicable to human participant research. Key research personnel must promptly and effectively interact with the PI and, when designated by the PI, the IRB, providing all information necessary to permit initial and continuing review of research. By signing the Food and Drug Administration (FDA) Form 1572 or Investigator Agreement, the PI assures federal regulators that a qualified IRB, which complies with the regulations, will review and approve the research before it is initiated. Additionally, the PI agrees to obtain IRB approval of any changes to the protocol prior to their implementation unless the safety or welfare of the study subject is immediately at risk, and any

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materials used to recruit subjects. Furthermore, the PI agrees to promptly notify the IRB of any identified potential risks to subjects associated with the test article or study procedure(s).

**III. SCOPE:**

This SOP applies to key research personnel’s essential interactions with the IRB.

**IV. RESPONSIBILITY:**

This SOP applies to key research personnel involved in communicating with the IRB regarding clinical research conducted at Beaumont Health.

**V. GENERAL:**

**A. Compliance with IRB policies**

1. All key research personnel must be knowledgeable and adhere to IRB policies and reporting guidelines pertaining to their roles. Current versions of the IRB policies are on the Research Institute website.
2. Current IRB Membership Rosters are available on the IRB website and should be filed in the regulatory binder. Federally-funded studies require a copy of the Federal Wide Assurance Number (FWA) be filed in the regulatory binder.

**VI. PROCEDURES:**

**A. Communicating with the IRB at study start-up**

1. Complete the IRB application in iMedris, the IRB electronic submission system. Upload all attachments as directed on the submission form (e.g., protocol, investigator’s brochure, Informed Consent and Authorization Document, advertisements, etc.).
2. Following IRB review of submitted materials, review the written decision of the committee regarding approval status (i.e., approved, modifications required, deferred or disapproved), as communicated via email.
3. The IRB may request revisions and clarifications of the protocol or associated documents. Provide written responses to the IRB in iMedRIS and gain sponsor approval of any IRB-requested changes.
4. Receive written documentation of IRB approval of the protocol and Informed Consent and Authorization Document prior to the initiation of any research-related activities. Provide documentation to the sponsor/contract research organization (CRO).
5. Maintain all documents in the appropriate study files.

**B. Communicating with the IRB while the study is ongoing**

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1. In accordance with IRB Policy [Amendment Requests to the IRB Approved Studies](#):
  - a. Prospectively notify the IRB of any changes to the protocol and/or Informed Consent and Authorization Document and of any new information regarding the test article, using the Amendment Request Form in iMedRIS.
  - b. Receive written documentation of IRB approval of amendments and associated revisions to study-related documents prior to implementation. Provide documentation to the sponsor/contract research organization (CRO).
2. In accordance with IRB Policy [Reporting an Unanticipated Problem Involving Risk to Participants or Others](#):
  - a. Notify the IRB of all on-site and off-site Unanticipated Problems which meet the IRB reporting requirements, using the iMedRIS Unanticipated Problem (UP) Reporting Form, within seven days (one week) of key research personnel knowledge. Only those off site incidents that the sponsor reports to a federal agency as an “Unanticipated Problem” should be reported. Submit information from the sponsor showing the UP has been reported to the federal agency.
3. In accordance with IRB Policy [Protocol Deviations](#):
  - a. Promptly inform the IRB of protocol deviations which meet IRB reporting criteria utilizing the Protocol Deviation Report Form within seven days (one week).
4. In accordance with IRB Policy [Continuing Review and Renewal of a Protocol](#):
  - a. Submit continuing review documents, including Progress Report Forms in iMedRIS so the protocol may be reviewed at the IRB meeting prior to expiration deadline, to avoid lapse in IRB approval.
5. Maintain all documents in the appropriate study files.

**C. Communicating with the IRB when the study is closed**

1. In accordance with IRB Policy [Study Completion, Closure or Expiration](#):
  - a. Submit a Final Report/Closure Form in iMedRIS when the study is closed.
  - b. Notify the sponsor/CRO once the study has been closed with the IRB.

**D. Communication received from the IRB**

1. Communications from the IRB will be received via email. Consent, assent and related documents will be stamped with an expiration date.

**E. Communication with the IRB for one-time emergency use of test article for a single patient**

1. In accordance with IRB Policy [Emergency Use of a Test Article](#):
  - a. Ensure the criteria outlined in the IRB policy have been met.
  - b. Notify the IRB of the emergency use within five working days of the use, and preferably prior to the use.

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- c. To secure a waiver from the IRB for emergency use, submit the following:
  - 1) An iMedRIS application for the intended emergency use of the device or drug.
  - 2) Within the application, include a description of the request, the nature of the life-threatening situation and confirm there is no alternative treatment available.
  - 3) A letter of concurrence from a non-involved physician within five (5) days following the use, and preferably prior to the use.
  - 4) A letter to the sponsor.
  - 5) The Informed Consent and Authorization Document.
  - 6) The protocol.
  - 7) Any other supporting documentation that will help explain the situation.
- d. A follow-up report must be submitted within five (5) working days after the use of the test article.
  - 1) If prior approval for the emergency use of the test article was not obtained, the follow-up report should be included in the initial notification to the IRB.
  - 2) If the protocol and Informed Consent and Authorization Document were not submitted prior to the use of the test article, these documents must accompany the five (5) day follow-up report.
- e. The IRB will prepare a letter of acknowledgement of the emergency use, and an acceptance stamp on the consent form and return these documents to the requesting physician.

## **VII. APPLICABLE REGULATIONS AND GUIDELINES:**

21 CFR 312.32 IND safety reports  
 21 CFR 312.53 Selecting investigators and monitors  
 21 CFR 312.54 Emergency research  
 21 CFR 312.66 Assurance of IRB review  
 21 CFR 50 Protection of Human Subjects  
 21 CFR 56 Institutional Review Boards  
 45 CFR 46 Protection of Human Subjects  
 FDA Information Sheets, 1998 Update: Frequently Asked Questions, Guidance for Institutional Review Boards and Clinical Investigators  
 FDA Information Sheets, October 1998: Frequently Asked Questions, Continuing Review After Study Approval  
 International Conference on Harmonisation; Good Clinical Practice: Consolidated Guideline, May 1997

## **VIII. REFERENCES TO OTHER APPLICABLE SOPs:**

Research Administration Policy [\*Responsibilities of the Principal Investigator\*](#)  
 Clinical Research Policy [\*Responsibilities of the Research Team\*](#)

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- Clinical Research Policy [Site-Sponsor/Contract Research Organization \(CRO\) Communications](#)
- Clinical Research Policy [Regulatory Files and Study Subject Records](#)
- IRB Policy [Informed Consent and Authorization in Research](#)
- IRB Policy [Reporting an Unanticipated Problem Involving Risk to Participants or Others](#)
- IRB Policy [IRB Initial Review of Research Protocols](#)
- IRB Policy [226 PI Notification of Review Outcomes and Response Requirements](#)
- IRB Policy [Research Exempt from Full IRB Review](#)
- IRB Policy [Study Completion, Closure or Expiration](#)
- IRB Policy [Expedited Review of Research](#)
- IRB Policy [201 Amendment or Corrections of Documentation](#)
- IRB Policy [Amendment Requests to the IRB Approved Studies](#)
- IRB Policy [Protocol Deviations](#)
- IRB Policy [Continuing Review and Renewal of a Protocol](#)
- IRB Policy [Emergency Use of a Test Article](#)

## **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.