

Title: <b>Correction of Documentation</b>	*Applicable to: <b>Beaumont Health</b>	Effective Date: <b>01/11/2018</b>
		Last Periodic Review Date: <b>01/11/2018</b>
Policy Owner: <b>Administrative Director</b>	Document Type: <b>Policy</b>	Functional Area: <b>IRB and Clinical Research, 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:**

The purpose of this policy is to establish a procedure for correcting, amending or altering Institutional Review Board (IRB) documentation. This policy is not intended to address revisions to the research protocol or operational changes in how the research will be conducted (see Policy [Amendment Requests to the IRB Approved Studies](#)).

**II. SCOPE:**

This policy applies to all documents submitted to the IRB, principal investigators (PI), key personnel, research staff, IRB members and IRB staff.

**III. GENERAL:**

The IRB is responsible for the review (initial and continuing) and oversight of research involving human participants at Beaumont Health. To provide an objective and thorough review of the research and supporting documents, the committee requires accurate information. Occasionally, inaccurate information is submitted to the IRB in error and later corrected. The IRB documentation must reflect the correction. For example:

- A. An outdated patient information brochure is submitted as part of the original application. When the error is recognized, the PI resubmits the current brochure with a written explanation of the error and correction. The IRB issues a letter acknowledging receipt and acceptance of the updated brochure.

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- B. The PI becomes aware of a typographical error in the IRB application some months after the project has received IRB approval. The PI notices disease prevalence was listed as 80% when it is actually 90%. The PI submits an amendment explaining the error. The IRB issues a letter acknowledging receipt of this corrected information and lists required actions, if any.

The IRB may make errors in documents which are later discovered and corrected. The IRB file must reflect all such corrections. Errors may be corrected by memos or letters issued from the IRB. All documentation corrections must be made by an IRB staff person in writing and documented in the IRB electronic record for the study. The errors are corrected in iMedRIS either by a new letter being issued, Note to File uploaded, or a note in IRB notebook. For example:

- A. The IRB issues a letter. Later, a typographical error of the approval date is noticed. The IRB re-issues the letter with the corrected date and a memo explaining the error and the correction is stored in IRB notebook. The letter is provided to the PI for the study file and placed in the IRB file. The original letter, bearing the incorrect date is voided in iMedRIS, and the change is recorded and dated by the IRB staff person making the correction.

**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.