

Title: <b>Research Record Retention and Destruction</b>	*Applicable to: <b>Beaumont Health</b>	Effective Date: <b>03/19/2018</b>
Policy Owner: <b>Administrative Director</b>	Document Type: <b>Policy</b>	Last Periodic Review Date: <b>03/19/2018</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 the retention of research records for human participant research conducted at Beaumont Health (Beaumont). The Beaumont Health (Beaumont) IRB serves as the primary Institutional Review Board for human participant research conducted at Beaumont (for information about the use of external IRB's, see policy [Review by an External Institutional Review Board](#)). Storage and retention of research data must follow the local requirements for the local IRB and Beaumont Research Institute.

**II. SCOPE:**

This policy applies to investigators, key research personnel, Institutional Review Board (IRB) members, IRB staff and Research Administration staff. This policy applies to all types of records, including both paper and electronic.

**III. PROCEDURE:**

A. Beaumont requires investigators to maintain research records, for approved human participant protocols, in accordance with all federal and institutional requirements including but not limited to the HIPAA Privacy Rule, the Food and Drug Act and Medicare policy. The stored data must

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be kept in a secure, protected manner within a Beaumont facility, or with an approved vendor e.g., Iron Mountain.

All investigators using protected health information (PHI) from research participants are required to retain study records, minimally, for eleven (11) years beyond study completion. The storage of research records is the responsibility of the principal investigator and should be incorporated into study design and budget development. Studies enrolling pediatric patients require study records to be retained until the last participants turns 21 years of age.

Students, residents and fellows who hold electronic research data are required to store the data in a study specific folder on SharePoint.

When a participant withdraws from a clinical trial:

1. The data collected about the participant to the point of withdrawal remains part of the study database and may not be removed. The consent document may not give the participant the option of having data removed.
2. An investigator may ask a participant who is withdrawing whether the participant wishes to provide continued follow-up and further data collection subsequent to their withdrawal from the interventional portion of the study. Under this circumstance, the discussion with the participant would distinguish between study-related interventions and continued follow-up of associated clinical outcome information, such as medical course or laboratory results obtained through noninvasive chart review, and address the maintenance of privacy and confidentiality of the participant’s information.
3. If a participant withdraws from the interventional portion of the study, but agrees to continued follow-up of associated clinical outcome information as described above, the investigator must obtain the participant’s informed consent for this limited participation in the study (if the situation has not been described in the original informed consent document). IRB approval of the informed consent documents would be required.
4. If a participant withdraws from the interventional portion of a study and does not consent to continued follow-up of associated clinical outcome information, the investigator must not access, for purposes related to the study, the participant’s medical record or other confidential records requiring the participant’s consent. However, an investigator may review study data related to the participant collected prior to participant’s withdrawal from the study, and may consult public records, such as those establishing survival status.

**B. Exceptions** - In the event the validity of published data is questioned, investigators must preserve original data until such questions have been resolved to the satisfaction of Beaumont and any involved governmental agencies.

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### C. Record Destruction

1. **Paper Files:** The paper recycling program is the Beaumont approved document destruction process for all paper documents including those with patient information. Department managers are responsible for implementation of, and continued compliance with, Beaumont policy which includes:
  - a. Identifying documents for disposal in the hospitals paper recycling program or highly confidential disposal program.
  - b. Assuring documents containing patient information are disposed properly, and not disposed with regular office waste or trash.
  - c. Assuring documents containing patient information waiting for pick-up are retained in secure location.
2. **Electronic Files:** When planning the destruction of a database, registry or a repository which has been used for research or was intended for research use, submit an Amendment request to the IRB for review. Research Administration approval is also required.

### IV. REFERENCES:

21 CFR 312.61 Records  
 21 CFR 812.149 Records  
 45 CFR 164.528 Accounting of Disclosures of PHI

### V. ASSOCIATED POLICIES:

RI Policy [\*Responsibilities of the Principal Investigator\*](#)  
 IRB Policy [\*Using Databases, Repositories and Registries in Research\*](#)  
 RI Policy [\*Regulatory Files and Study Subject Records\*](#)  
 Beaumont Health Policy [\*Document Retention Policy and Procedures\*](#)  
 Beaumont Health Policy [\*Document Retention Guide - Copyrighted Material Do Not Print\*](#)  
 IRB Policy [\*Review by an External Institutional Review Board\*](#)

### 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.