

Title: Definition of Beaumont Health Research	*Applicable to: Beaumont Health	Effective Date: 01/11/2018
Policy Owner: Administrative Director	Document Type: Policy	Last Periodic Review Date: 01/11/2018 Functional Area: Research Administration, 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 AND OBJECTIVE:

The purpose of this policy is to define research subject to Beaumont Health policy and oversight.

II. POLICY STATEMENT/SCOPE:

A. Research subject to the regulatory oversight of Beaumont Health is defined as any human, animal or basic investigation characterized by any of the following:

1. The research is based on care delivered within Beaumont Health facilities (e.g., its hospitals, outpatient centers, extended care facilities, or other facilities partially but not exclusively owned by Beaumont Health), or
2. The research is supported by the use of Beaumont Health resources such as research equipment, or
3. The research is the work product of its employees, or
4. The basis of the research is clinical material obtained at a Beaumont Health facility, or
The research is based on Beaumont Health clinical care records

B. Such work is subject to all the rules, policies and regulations governing research at Beaumont Health.

III. PROCEDURE:

A. Below are examples of what constitutes research subject to Beaumont Health policies. This list is intended to be illustrative rather than fully comprehensive:

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Clinical research conducted at, or based on care provided at Beaumont Health facilities.

1. Outcomes and registry studies irrespective of the site of data collection (for example in a private practice office), wherein the matter being investigated is a surgical procedure or intervention that took place at a Beaumont Health facility.
 2. Studies proposing to make use of clinical or other records of care provided at a Beaumont Health facility by an outside institution or individual(s) require a data transfer agreement which is approved by Beaumont Health Research Administration before such information can be provided to the outside entity.
 3. Studies proposing to use clinical specimens obtained at a Beaumont Health facility or in particular from the Beaumont BioBank require an agreement which is approved by Beaumont Health Research Administration before such material can be provided to the outside entity.
 4. Studies in which the investigator or key personnel are full time Beaumont Health employees, residents or fellows are subject to this policy. If the research work is being conducted by a part time employee within the scope of their employment, these studies are also subject to this policy irrespective of the site of the research.
 5. All other health care professionals such as medical school faculty, other academic faculty and students (medical, nursing or other allied health) or any individual conducting research involving Beaumont Health facilities, supported by Beaumont Health, or utilizing Beaumont Health resources or patient records, are subject to provisions governing the conduct of research at Beaumont Health.
- B. Research that is independent of Beaumont Health policies and oversight, by way of example include the following:
1. Instances wherein Beaumont Health provides a clinical service (e.g., blood work, imaging) for research taking place outside of Beaumont Health, or when Beaumont Health is determined not to be engaged in research per federal regulations. See Research Administration policy 120 Institutional Engagement.
 2. Independent physicians with an appointment at a Beaumont Health institution or individuals employed less than full-time by Beaumont Health who are conducting research in a private practice setting when the research does not involve use of any Beaumont Health resources as stipulated above are not subject to Beaumont Health oversight.

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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.