Title: **Institutional Engagement in Research**	*Applicable to: **Beaumont Health**	Effective Date: **01/12/2018** Last Periodic Review Date: **01/12/2018**
Policy Owner: **Administrative Director**	Document Type: **Policy**	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:

The purpose of this policy is to provide guidelines for determining when Beaumont is considered to be "engaged" in human participant research, per the Department of Health and Human Services, Office of Human Research Protection (OHRP) Guidance on Engagement of Institutions in Human Subjects Research, October 16, 2008.

II. SCOPE:

This procedure applies to all principal investigators engaged in human participant research where the research occurs *outside* of Beaumont Health and where Beaumont is not engaged in the research (as defined below), Beaumont Administration, Research Institute (RI) staff and the Beaumont Health Institutional Review Board.

Beaumont research encompasses all laboratory-based, translational and clinical research conducted at Beaumont utilizing Beaumont facilities, equipment, patients or staff. Any investigation involving human participants at Beaumont, (including retrospective studies of specimens or medical records) requires prior review and approval by an IRB, either Beaumont's IRB or, when certain criteria is met, an approved external IRB.* This includes but is not limited to:

1. Research based on care delivered within Beaumont Health facilities (its' hospitals, outpatient centers, extended care facilities, or other facilities partially but not exclusively owned by Beaumont).
2. Research supported by the use of Beaumont resources such as research equipment.
3. Research which is the work product of Beaumont employees.

4. Research based on clinical material obtained at a Beaumont facility.
5. Research based on Beaumont clinical care records.

*For more information about studies eligible for external review, see IRB policy 233, *Review by an External Institutional Review Board*.

III. DEFINITIONS:

A. **Research** is defined as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

B. **Human subject/participant** means a living individual about whom an investigator (whether professional or student) conducting research obtains:
- data through intervention or interaction with the individual; or
- identifiable private information.

C. **Intervention** includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the participant or the participant's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and participant.

D. **Private information** includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human participants.

E. **Institution** is defined in 45 CFR 46.102(b) as any public or private entity or agency (including federal, state, and other agencies). For purposes of this policy, an institution's *employees or agents* refers to individuals who:
- act on behalf of the institution;
- exercise institutional authority or responsibility; or
- perform institutionally designated activities.

"Employees and agents" can include staff, students, contractors, and volunteers, among others, regardless of whether the individual is receiving compensation.

F. **Key Personnel** are individuals involved in the design, conduct, reporting or direct oversight of research involving Beaumont patients, facilities and/or other Beaumont resources including records and databases.

IV. BACKGROUND:

Determining Beaumont is Not Engaged in Human Participant Research

Per HHS OHRP guidance, an institution would be considered **not** engaged in a human participant research project if the involvement of their employees or agents in that project is limited to specific conditions, described below. **All** of the following conditions must be met:

1. The services performed do not merit professional recognition or publication privileges; and
2. The services performed are typically performed by those institutions for non-research purposes; and
3. The institution's employees or agents do not obtain informed consent for the research.
4. The institution's employees or agents do not administer any study intervention being tested or evaluated under the protocol.

The following sample scenarios describe types of institutional involvement when an institution is **not** engaged in human participant research, assuming the services would not merit professional recognition or publication privileges:

- An appropriately qualified laboratory whose employees perform routine serum chemistry analyses of blood samples for investigators as a commercial service.
- A transcription company whose employees transcribe research study interviews as a commercial service.
- A hospital whose employees obtain blood through a blood draw or collect urine and provide such specimens to investigators as a service.
- A radiology clinic, whose employees perform chest x-rays and send the results to investigators as a service.
- Institutions whose employees or agents:
  - Inform prospective participants about the availability of the research;
  - Provide prospective participants with information about the research (which may include a copy of the relevant informed consent document, information sheet and other IRB approved materials) but do not obtain subjects' consent for the research or act as representatives of the investigators;
  - Provide prospective participants with information about contacting investigators for information or enrollment; and/or
  - Seek or obtain the prospective participants' permission for investigators to contact them.

An example of this would be a clinician who provides patients with literature about a research study at another institution, including a copy of the informed consent document.

V. POLICY:

When standard of care clinical services (e.g., blood work, imaging, etc.) are requested of Beaumont for research being done outside of Beaumont, the Beaumont Service Line or Division administrator must verify or determine if the services requested by the research protocol are standard procedures. **Any time a standard diagnostic procedure must be modified to meet research protocol requirements, Beaumont would be considered "engaged" in the research, and Beaumont Health Institutional Review Board review and approval would be required.**

The Administrator of the Beaumont Service Line or Division providing the requested service is responsible for obtaining a completed **"Verification of Beaumont Non-Engagement in Outside Human Participant Research"** form, from the principal investigator of the study. The completed form is signed by the outside investigator and the Administrator of each Service Line or Division service division providing diagnostic services for a non-Beaumont research protocol. Final signature is applied by Beaumont Research Institute Administration, confirming the project is not Beaumont research. A fully executed copy of the *Verification of Beaumont Non-Engagement in Outside Human Participants Research* (Appendix A) form will be returned by Research Administration to all signatories.

The Service Line or Division Administrator providing the clinical diagnostic service will be responsible for making all arrangements for provision of the service, including administrative operations (e.g., scheduling, registration, providing results, etc.) and financial operations (e.g., establishing fair market value pricing, billing process, etc.). All arrangements must be consistent with the requirements of federal regulations, including Stark and Anti-Kickback statutes. Questions on this policy can be directed to Research Administration at 248 551-8550.

VI. ASSOCIATED POLICY AND GUIDELINES:

Research policy 222 *Institutional Authority*
OHRP Guidance on Engagement of Institutions in Human Subjects Research, October 16, 2008

VII. ATTACHMENTS: (see attachment tab, upper right corner)

Verification of Beaumont Non-Engagement in Outside Human Subjects Research Form

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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.