

Title: Defining Human Participant Research	*Applicable to: Beaumont Health	Effective Date: 04/03/2018
Policy Owner: Administrative Director	Document Type: Policy	Last Periodic Review Date: 04/03/2018 Functional Area: IRB and Clinical Research, 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 define human participant research as it pertains to Institutional Review Board (IRB) review of project submissions.

II. SCOPE:

This policy applies to investigators, key research personnel, IRB members and IRB staff, and all human research (detailed in Research policy [Definition of Beaumont Health Research](#)) characterized by any of the following:

- A. 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).
- B. Research supported by the use of Beaumont resources such as research equipment.
- C. Research which is the work product of Beaumont employees.
- D. Research based on clinical material obtained at a Beaumont facility.
- E. Research based on Beaumont clinical care records.

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The only exception to this policy is when Beaumont is determined not to be engaged in research per Research Policy [*Institutional Engagement in Research*](#).

Any investigation involving human participants at Beaumont (including retrospective studies of specimens or medical records) requires prior review and approval by an IRB. Unless specifically authorized, all human participant research must be submitted for review and approval to the Beaumont IRB.

III. **BACKGROUND:**

Federal regulations require an IRB review and have authority to approve, require modifications, or disapprove all research activities involving human participants. The Beaumont Health IRB is the IRB of record for Beaumont. The regulations do **not** apply to studies which do not meet the federal regulations’ definition of human participant research.

IV. **POLICY:**

The IRB will determine if a proposed study meets either the Department of Health and Human Services (HHS) or the Food and Drug Administration (FDA) definition of human participant research (clinical investigation). The study must meet the criteria for both research and human participants. If the study does not meet the definition provided below, a letter will be sent to the Principal Investigator (PI) stating the reason the project does not meet human participants review criteria.

A. **HHS Definition of Research** - Research is defined by the HHS as a **systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge**. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities.

For the purpose of this policy **“systematic investigation” is defined as a project in which a coherent body of ideas or principles is used to develop or contribute to a hypothesis**. For the purpose this policy **“generalizable knowledge” is defined as the use of data to draw conclusions which can be related to a larger entity**.

Examples of research projects include, but are not limited to:

1. Pilot studies.
2. Activities to refine a research tool(s) in preparation for a study.

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3. Chart review of three (3) or more patients.
4. Comparative studies.
5. Survey studies.
6. QA/QI projects which include a research component (Refer to IRB policy [Quality Assurance / Quality Improvement Projects](#)).
7. Medical intervention studies.
8. Studies conducted with the intent to publish findings.

Examples of projects **not** considered to be research include, but are not limited to:

1. Retrospective clinical case reports of two (2) or fewer patients. If these case reports are being combined with other case reports at Beaumont or an outside institution, the combination is considered research.
2. QA/QI investigations developed for a specific organizational unit at BHS with no intent to publish or disseminate findings beyond the unit or organization.
3. Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information that focus directly on the specific individuals about whom the information is collection.
4. Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health author. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in disease, or increases in injuries from using consumer products).
Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).
5. Collection and analysis of information, biospecimens or records by or for a criminal justice agency for activities authorized by aw or court order solely for criminal justice or criminal investigative purposes.
6. Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

- B. HHS Definition of Human Participant - A human participant is defined by HHS as living individual about whom an investigator (whether professional or student) conducting research:**

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1. Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies or analyzes the information or biospecimens; or
2. Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

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

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

Data or specimens are not considered to be individually identifiable when they cannot be linked to specific individuals by the PI either directly or indirectly through coding systems. The activity is not considered to involve human participants if the following conditions are **both** met:

1. The private information or specimens were not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; and
2. The investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain because:
 - a. The investigators and the holder of the key enter into an agreement prohibiting the release of the key to the investigators under any circumstances, until the individuals are deceased; **or**
 - b. There are other legal requirements prohibiting the release of the key to the investigators, until the individuals are deceased. (OHRP Coded Private Information or Specimens Use in Research, Guidance).

C. FDA Definition of Research (Clinical Investigation) An activity is defined as **research** by the FDA regulations when it involves an FDA regulated test article as described below:

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“Research” as defined by FDA regulations is a clinical investigation and means any experiment which involves a test article and one or more human participants, and either must meet the requirements for prior submission to the FDA under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act, or need not meet the requirements for prior submission to the FDA under these sections of the Federal Food, Drug, and Cosmetic Act, but the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit. The terms research, clinical research, clinical study, study, and clinical investigation are synonymous for purposes of FDA regulations. [21 CFR 50.3(c), 21 CFR 56.102(c)]

1. Experiments must meet the requirements for prior submission to the FDA under section 505(i) of the Federal Food, Drug, and Cosmetic Act means any use of a drug other than the use of an approved drug in the course of medical practice. [21 CFR 312.3(b)]
2. Experiments must meet the requirements for prior submission to the FDA under section 520(g) of the Federal Food, Drug, and Cosmetic Act means any activity that evaluates the safety or effectiveness of a device. [21 CFR 812.2(a)]
3. Any activity in which results are being submitted to or held for inspection by FDA as part of an application for a research or marketing permit is considered to be FDA-regulated research. [21 CFR 50.3(c), 21 CFR 56.102(c)]

D. FDA Human Participant - The FDA defines a human participant as an **individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A participant may be either a healthy human or a patient.** For medical device research an individual whose specimen has been or will be used with an investigational device or as a control is considered a human participant.

E. Department of Defense Definition of “Experimental” Participant - Research involving a human being as an experimental participant. An activity, for research purposes, where there is an intervention or interaction with a human being for the primary purpose of obtaining data regarding the effect of the intervention or interaction. Examples of interventions or interaction include, but are not limited to, a physical procedure, a drug, a manipulation of the participant or participant’s environment, the withholding of an intervention that would have been undertaken if not for the research purpose.

F. Activities Not Meeting the Criteria for Human Participants Research - If the activity is not subject to either HHS regulations or to FDA regulations because it does

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not fit the definition of human participant research provided above, the PI may conduct the activity without submission to IRB.

G. Assistance Determining Human Participant Research - Many publications require evidence of IRB review or concurrence the project does not meet the requirements for review. To determine whether a project meets the definition of human participant research and thus requires IRB approval, investigators should complete the *Determining Human Participant Research* section in iMedRIS. The IRB will review and provide a written determination as to whether the stated activities constitute human participant research. Questions used by the IRB to make this determination are as follows:

1. Do the proposed activities involve a systematic approach?
2. Is the intent of the proposed activities to develop or contribute to generalizable (scholarly) knowledge?
3. Do the activities involve obtaining information about living individuals? If yes, do the activities involve intervention or interaction with the individuals (i.e., prospective collection of data/specimens)?
4. Do the activities involve obtaining individually identifiable and private information about living individuals?

V. REFERENCES:

- 21 CFR 50.3 Definitions
- 45 CFR 102 Definitions
- 21 CFR 56.108 (b) IRB Functions and Operations
- 45 CFR 46.108(b) IRB Functions and Operations
- 45 CFR 46.111 Criteria for IRB Approval of Research
- 21 CFR 56.111 Criteria for IRB Approval of Research
- 21 CFR 312.3(b)
- 21 CFR 812.2(a)
- 21CFR 56.102(c)

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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.