Beaumont®
William Beaumont Hospital

Subject		No.	Page
DEFINING HUMAN PARTICIPANT RESEARCH		**251**	1 of 4
Prepared By	Prior Issue Date	Issue Date	
Institutional Review Board	**5/26/13**	**6/10/16**	

PURPOSE

The purpose of this policy is to define human participant research as it pertains to Institutional Review Board (IRB) review of project submissions.

SCOPE

This policy applies to investigators, key research personnel, IRB members and IRB staff, and all human research (detailed in Research policy 126 *Definition of Beaumont Research*) characterized by any of the following:

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.

The only exception to this policy is when Beaumont is determined not to be engaged in research per Research Policy 120 *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.

BACKGROUND

Federal regulations require an IRB review and have authority to approve, require modifications, or disapprove all research activities involving human participants. The Beaumont 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.

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.

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.**

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.**

Beaumont®
William Beaumont Hospital

Subject		No.	Page
DEFINING HUMAN PARTICIPANT RESEARCH		**251**	2 of 4
Prepared By	Prior Issue Date	Issue Date	
Institutional Review Board	**5/26/13**	**6/10/16**	

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

- Pilot studies.
- Activities to refine a research tool(s) in preparation for a study.
- Chart review of three (3) or more patients.
- Comparative studies.
- Survey studies.
- QA/QI projects which include a research component (Refer to IRB policy 230 *Quality Assurance/Quality Improvement Projects*).
- Medical intervention studies.
- Studies conducted with the intent to publish findings.

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

- 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.
- QA/QI investigations developed for a specific organizational unit at BHS with no intent to publish or disseminate findings beyond the unit or organization.

HHS Definition of Human Participant

A human participant is defined by HHS as a living individual about whom an investigator (whether professional or student) conducting research obtains:

1. **Data through intervention or interaction with the individual, or**
2. **Identifiable private information.**

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:

Beaumont®
William Beaumont Hospital

Subject		No.	Page
DEFINING HUMAN PARTICIPANT RESEARCH		**251**	3 of 4
Prepared By	Prior Issue Date	Issue Date	
Institutional Review Board	**5/26/13**	**6/10/16**	

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 *Guidance on Research Involving Coded Private Information or Biological Specimens* found at http://www.hhs.gov/ohrp/policy/cdebiol.html).

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:

"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)]

- 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)]
- 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)]
- 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)]

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.

Beaumont®
William Beaumont Hospital

Subject		No.	Page
DEFINING HUMAN PARTICIPANT RESEARCH		**251**	4 of 4
Prepared By	Prior Issue Date	Issue Date	
Institutional Review Board	**5/26/13**	**6/10/16**	

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

☐ Original ☒ Revision or Review

Research Institute Compliance Committee Review Date: _____

Corporate Administration Approval: _____ Date: _____
V.P. of Research or Chief Medical Officer

Research Institute Board Approval: _____ Date: _____

Research Administration Approval: _____ Date: _____
Administrative Director

Research Institute Administration