| Title: **Quality Assurance / Quality Improvement Projects** | *Applicable to: **Beaumont Health** | Effective Date: **01/12/2018**<br>Last Periodic Review Date: **01/12/2018** |
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| Policy Owner: **Administrative Director** | Document Type: **Policy** | 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 provide guidance in identifying when a project, which may include data collection and analysis of health service activities, meets the definition of human participant research. All projects meeting the criteria for human participant research must be reviewed by the Beaumont Health Institutional Review Board (IRB) prior to study initiation.

## II. SCOPE:

This policy applies to all individuals involved in quality assurance/ quality improvement (QA/QI) projects or research at Beaumont Health.

## III. GENERAL:

A. In accordance with federal regulations, International Conference on Harmonization, Good Clinical Practice Consolidated Guideline (ICH GCP), Beaumont policies, and Research Institute Bylaws, an IRB must be responsible for the initial and continuing review and oversight of research involving human participants at Beaumont. The IRB does not routinely review internal audits or reviews of Beaumont operations which are identified as QA/QI projects when the results are not intended to be shared outside the corporation. However, there are times when QA/QI projects have characteristics which meet the criteria for

classification as human participant research requiring IRB review and oversight.

B. All submissions to the IRB for review of research activities must be made using the appropriate IRB submission forms. For further guidance, refer to IRB Policy *IRB Initial Review of Research Protocols* .

C. QA/QI projects involve health services data collection and analysis of activities which are not intended to generate scientific knowledge. Instead, the activities are used as a management tool to improve the provision of services to a specific health care population. Activities not intended to have specific application beyond Beaumont are generally referred to as program evaluation or QA/QI projects. Data sharing or benchmarking for purposes of measuring the performance of internal programs, must comply with HIPAA guidelines.

D. Occasionally, internal quality projects (i.e., those initiated at Beaumont without intention of sharing data with other institutions, associations, registries, etc.) result in unexpected generalizable knowledge and the project leader wishes to publish the results. Many medical journals, associations and related groups require documented evidence of prospective IRB approval before they consider articles for publication. Articles based on data collected at Beaumont without prospective approval from Beaumont's IRB may be deemed ineligible for publication. When publication or presentation outside of Beaumont is a possibility, IRB review and approval should be carefully considered. If unsure whether a project meets the definition of "research", the *Human Participant Determination Form* may be completed to request IRB evaluation of the activity to determine status as human participant research or not human participant research.

## IV. POLICY:

When a QA/QI project meets the criteria for human participant research, the project is considered research and must be prospectively reviewed by the IRB. Further, all QA/QI projects sharing data externally must be reviewed by the External Data Sharing Review Committee prior to IRB submission.

A. **External Data Sharing Committee -** The External Data Sharing Committee is a corporate committee comprised of representatives from Privacy, Information Security, the IRB, Legal Affairs and External Quality Measures Department. This Committee reviews projects to determine if IRB review is required, if the project is HIPAA compliant, if the process for data sharing is secure and to assure the proper legal agreements are in place.

B. **Defining Activities as Research and/or QA/QI -** When QA/QI project data is being shared externally (i.e., with another institution, academic association, registry, etc.) project managers or investigators must request an evaluation by the External Data Sharing Review Committee by submitting the form titled *Request to Send External Entities Beaumont Health Clinical Data to the External Data* sharing Committee. The final determination of whether or not the activity is research is the responsibility of the External Data Sharing Review Committee and the IRB.

C. **QA/QI Activity without a Research Component -** When the purpose of an activity is strictly to measure the effectiveness of an established process, program or service in achieving its objectives, and the information gained from the evaluation will be used to provide feedback to improve the program the activity is not human participant research. The activity is a management tool for monitoring and improving the program. Information learned has immediate benefit for the program and/or clients receiving the program or services.

D. **QA/QI Activity with a Research Component -** The Department of Health and Human Services (HHS) defines research as a systematic investigation, including research development, testing and evaluation designed to develop or contribute to generalizable knowledge. For research purposes, a human participant is defined as a living individual about whom an investigator conducting research obtains; 1) data through intervention or interaction with the individual, or 2) identifiable private information. Human participant research can include a variety of activities, such as experiments, observation, surveys, tests and recordings.

Examples of QA/QI activities with a research component include:

1. When a quality improvement project involving human participants is undertaken to test a new, modified, or previously untested clinical intervention, service, or program to determine whether it is effective as a new or revised standard of care, and can be used elsewhere, the activity is research.
2. The systematic comparison of standard or non-standard interventions involving human participants is also research (National Bioethics Advisory Commission).
3. The development of a database for QA/QI activities when there is also an intention of conducting generalizable research using the same data.
4. Collecting additional data beyond what is required for a QA/QI project with the intention of using the data for research purposes.

E. **Corporate Quality Registries -** Corporate quality registries overseen or reviewed by Corporate Quality, Safety and Clinical Effectiveness may qualify for IRB oversight by the lead organizations' designated IRB after approval from the External Data Sharing Review Committee. The IRB must hold and maintain AAHRPP accreditation (Association for the Accreditation of Human Research Protection Programs). Refer to IRB Policy *Review by an External Institutional Review Board* for additional information on criteria for relying on an external IRB. An IRB approval letter from the lead organization must be sent to the External Data Sharing Review Committee by the interested Beaumont lead physician or project manager wishing to participate in a collaborative QA/QI project.

Some federally sponsored registries, typically thought to require IRB review under the Expedited Review Categories, may meet the criteria for Exemption Category 5. This Category includes activities subject to the approval of department or agency heads, which are designed to study, evaluate or otherwise examine:

1. Public benefit or service programs e.g. financial or medical benefits as provided under the Social Security Act or service (e.g., social, supportive, or nutrition services as provided under the Older Americans Act);
2. Procedures for obtaining benefits or services under these programs is conducted pursuant to specific federal statutory authority;
3. Possible changes in or alternatives to those programs or procedures; or
4. Possible changes in methods or levels of payment for benefits or services under those programs.
5. There is no statutory requirement an IRB has to review the research.
6. The research does not involve significant physical invasions or intrusions upon the privacy of participants (see IRB Policy *Research Exempt from Full IRB Review*).

It is the responsibility of the Corporate Quality, Safety and Clinical Effectiveness department overseeing the registry to assure only those qualified by education, experience (and licensure if applicable), extract data from hospital records and conduct registry data entry. Given the position structure and levels of oversight and data monitoring, individuals whose roles on the registry are limited to data extraction and entry will not be considered key personnel and will not require IRB approval. This exception applies only to registries managed by Corporate Quality, Safety and Clinical Effectiveness.

Alteration of national registries to add data variables not required by the registry (i.e., Beaumont specific research fields), will result in the project meeting the definition of Beaumont research requiring Beaumont IRB approval.

If a Beaumont researcher wishes to use the data outside of the registry for generalizable research purposes, this use will qualify as an independent research project requiring IRB review and approval.

## V. PROCEDURE:

A. **Research Activity -** To determine whether a project meets the definition of human participant research and therefore requires IRB approval, investigators should submit all documents received that relate to the project to the External Quality Measures Department for review by the External Data Sharing Review Committee. Documents required with submission include, but are not limited to, the protocol, project description, data collection forms, acknowledgement of participation letters, and data sharing agreements or legal contracts received from the project sponsor. If the project is deemed to qualify as research, the investigator will complete an IRB application via iMedRIS, the IRB electronic submission system.

B. **QA/QI Activity -** Projects conducted strictly for QA/QI purposes are not considered research because:
1. Their purpose is not to test new phenomenon.
2. They require procedures a patient would normally undergo, given his/her condition.
3. They do not compare interventions.
4. They do not develop generalizable knowledge.
5. They involve no additional risks to patients/participants.

Such QA/QI projects are mechanisms to assure Beaumont functions optimally, and are generally performed for internal process improvement purposes. An answer of "YES" to all three of the following questions identifies a QA/QI study which **does not** require IRB review.
1. Will physicians and caregivers continue to provide their routine standard clinical care regardless of the conduct of the project?
2. Does the project involve collection of data to which the investigator has routine or authorized access as part of his or her employment or assigned responsibilities within the hospital/department?
3. Are the results intended to be used within Beaumont only or shared with a national or regional registry?

<u>QA projects must not:</u>
1. Infringe on a patient's privacy, (i.e., a person's right to be left alone), **or**

2. Breach patient confidentiality (i.e., information meant to be kept secret), **or**
3. Pose any risk to patients, facility, or staff.

Examples to assist you:

**Example One:**
The Emergency Center (EC) management team decides to evaluate patient wait times. They decide to track admissions and the length of time the patients wait for care on a given day. The purpose of this project is to evaluate timeliness of care, and whether additional staff may be needed.

1. This evaluation monitors an existing process (flow of patients through the EC).
2. There is no intervention in the clinical care provided to the patients.
3. Information about the number of patients seen in the EC is routinely available to designated managerial staff responsible for providing efficient care in the EC.
4. The results are intended to be used within Beaumont only (no planned publications or presentations and not to contribute to generalizable knowledge). This project is considered a QA/QI project and would not require IRB review and approval.

**Example Two:**
Same project as above, except the management group from the onset intends to analyze the results for presentation to a national managerial conference.

1. This evaluation monitors an existing process (flow of patients through the EC).
2. There is no intervention in the clinical care provided the patients.
3. Information about the number of patients seen in the EC is routinely available to designated managerial staff responsible for providing efficient care in the EC.
4. The results are intended to be disseminated outside of the organization, in an effort to contribute to generalizable knowledge.

This project would now require submission to the IRB because the intent of the project is to contribute to generalizable knowledge.

**Example Three:**
Same project as above with the addition of patients being randomized to one of two groups. Group 1 would be seen by a nurse within thirty (30) minutes of arrival, while Group 2 would have no expected timeframe for initial assessment by a nurse in the EC.

1. This evaluation monitors an existing process (flow of patients thru the EC).
2. There is an intervention – patients are being randomized to one of two Groups, which will modify the current process flow and perhaps have clinical implications.
3. Information about the number of patients seen in the EC is routinely available to designated managerial staff responsible for providing efficient care in the EC. This

project would now require IRB review, since it is testing a modified service to determine whether it is effective as a revised standard of care.

**Example Four:**

A new orthopaedic surgery technique has been developed, which appears promising, and CMS/Medicare is considering whether to cover the procedure. They have announced coverage with evidence development demonstration project which would provide Medicare coverage for the procedure at institutions which provide data to the registry. If the registry meets all criteria in Exemption Category 5, it may be exempt from ongoing IRB oversight. If it does not, it may require IRB review and approval, if deemed human participants research.

## VI. APPLICABLE REGULATIONS AND GUIDELINES:

21 CFR 50 – Protection of Human Subjects
21 CFR 56 – Institutional Review Boards
45 CFR 46 – Protection of Human Subjects

## VII. REFERENCES:

IRB Policy *Expedited Review of Research*
IRB Policy *IRB Initial Review of Research Protocols*
IRB Policy 222 *Institutional Authority*
IRB Policy *Research Exempt from Full IRB Review*
IRB Policy *Review by an External Institutional Review Board*
William Beaumont Hospital, Research Institute Bylaws

## 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.