MERCY HEALTH

INSTITUTIONAL POLICY & PROCEDURE
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TITLE: Institutional Review Board Review of Research
RR 413 Research versus Quality Improvement or Evidence Based Practice

ORIGINATOR: Institutional Official

APPROVAL: Institutional Official

POLICY STATEMENT: This policy establishes the definition of research versus quality improvement (QI) (also referred to as clinical quality measurement) or evidence based practice projects (EBP). The policy applies to all projects conducted at Mercy Health. Whenever there is uncertainty as to whether a project is considered research or QI, EBP project the project leader should request guidance from the Institutional Review Board (IRB).

DEFINITIONS:
Research: A systematic investigation including research development, testing and evaluation designed to develop or contribute to generalizable knowledge (45 CFR 46.102).
Quality Improvement: A systematic pattern of actions that is constantly optimizing productivity, communication, and value within an organization in order to achieve the aim of measuring the attributes, properties and characteristics of a product/service in the context of expectations and needs of customers and users of that product (The Institute of Medicine). Clinical quality improvement is an interdisciplinary process designed to raise the standards of the delivery of preventive, diagnostic, therapeutic, and rehabilitative measures in order to maintain, restore or improve health outcomes of individuals and populations.
Evidence Based Practice: A systematic search for and critical appraisal of the most relevant evidence to answer a clinical question. Evidence based practice requires a rigorous and scholarly approach using tools and strategies similar to those used in research, however, the focus is on utilizing the evidence that already exists rather than developing or contributing to generalizable knowledge.
Quality Assurance: A system for evaluating performance, as in the delivery of services or the quality of products provided to consumers, customers, or patients.

GENERAL PROVISIONS: Research projects must comply with specific policies and regulations designed to protect human participants and privacy rights. Quality improvement projects are not required to act in accordance with research policies and regulations. Evidence Based Practice Projects utilizes rigorous methodology but still fall under the realm of QI. Quality improvement in health care, unlike research, focuses on translating existing knowledge from varying levels of evidence into clinical practice to improve the quality of health care for individuals and populations. The key difference between these two concepts is that research studies are intended to create new knowledge that can be generalizable to other populations and settings, while QI in health care uses existing knowledge to improve health care outcomes within a local health care institution or setting. Sometimes it may be difficult to determine if a project is quality improvement or research. The determination may have significant impact on the project design, procedures and regulatory compliance requirements. Individuals that are unsure of whether a project is research or quality should inquire with the Mercy Health Regional IRB for review and guidance. Research conducted without Mercy Health Regional Institutional Review Board approval is reportable to federal authorities (FDA and OHRP).
One aspect of QI is quality assurance. The purpose of quality assurance is to ensure known quality. A quality assurance activity should present no risk to participants. A quality assurance activity is a mechanism to ensure that Mercy Health functions optimally. A quality assurance activity is usually used for internal auditing processes only. Quality assurance usually involves monitoring of an existing process for which there will be no manipulation of the existing process. The collection of data for a quality assurance activity usually involves the collection of data to which the investigator routinely has access to as part of his/her responsibilities within the institution. A project leader may routinely have access to the data for treatment, costs containment, performance or compliance purposes. Quality assurance activities must not infringe on a participant's privacy, breach a participant's confidentiality or pose any risk to the participant.

Another aspect of QI is implementation of evidence based practices that may be new to the organization. Evidence based practice involves the translation or application of the best evidence to clinical practice. Like quality assurance activities as described above, evidence based practice projects are intended for implementation within the organization. They may involve data collection and monitoring, and the project leader may routinely have access to the data for treatment, costs containment, performance or compliance purposes. Evidence based practice project activities must not infringe on a participants privacy, breach a participants confidentiality or pose any risk to the participant. When the purpose of an activity is to assess the success of an established program in achieving its objectives and the information gained from the evaluation will be used to provide feedback to improve that program, that activity is not human subject research. The evaluation is a management tool for monitoring and improving the widely accepted and evidence based programming. Information learned has immediate benefit for the program and/or clients receiving the program or services. When the quality improvement involving human participants is undertaken to test a new, modified, or previously untested or unproven (non-evidence based) intervention, service, or program to determine whether it is effective and can be used elsewhere, the activity is research. The systematic comparison of standard or non-standard interventions involving human participants also is research.

Since methods used in program evaluation, quality improvement, or assessment employ methods typically used in research, it may be challenging to determine whether or not the evaluation is considered research under the purview of the IRB. If your project fulfills the following criteria the project does not require IRB review:

1. The data collection and analysis activities are not intended to generate scientific knowledge, but rather are used as a management tool to improve the provision of services to a specific population, organization or program; AND
2. The activities that are examined are not intended to have any application beyond the organization or program that is the target or source of the evaluation; AND
3. The purpose of the activity is to assess the success of an established evidence based program in achieving its objectives and the information gained from the evaluation will be used to provide feedback, monitor and/or improve the program.

It is important for project leads to note that some journals and organizations require a letter of Quality Improvement/Quality Assurance Designation in order to approve the publication or presentation of the activity findings/data. Mercy Health Regional IRB requires that these types of designations be made prior to the QI/QA activity occurring. Mercy Health Regional IRB will not make the determination after an activity has been started or completed. It is important for project leads to have a publication and presentation plan prior to activity being started.

REFERENCE:
45 CFR 46.10

ATTACHMENTS:
RR 413-A Checklist: Clinical Quality Improvement Determination
RR 413-B Notice of Clinical Quality Improvement Measurement Designation
## Institutional Policy & Procedure

### PROCEDURE:

#### Responsibility

**Investigator / Project Leader**

1. Completes and submits the Request for QA/QI Designation in IRBManager, along with a written summary of the proposed activity.
2. Provides IRB with detailed information regarding proposed activity.
3. Completes all forms, checklists and tools as requested by the Office of the IRB.
4. Places IRB written response on file with activity or study records.

**IRB Specialist / IRB Coordinator**

1. Reviews incoming submissions and provides Requests for QA/QI Designation and submitted materials to the IRB Manager.
2. Issues correspondence as advised by the IRB Chairperson or designee.

**IRB Chairperson or Designee**

1. Reviews QA/QI designation request.
2. May request meeting with the project lead to further discuss the proposed activity.
3. May request data tools be provided to allow the review and evaluation of the proposed activity.
4. If project is determined to be quality improvement or quality clinical measurement activity that is not research, request issuance of the Notice of Clinical Quality Improvement Designation letter.
5. If project meets definition of human subjects research, request completion and submission of a full IRB initial application package.

**IRB Committee**

1. Reviews research studies as assigned.

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**CONCURRENT CONSENTS:**

Institutional Official

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