

# **Institutional Guidance Document**

## **Quality Assurance/Quality Improvement Projects**

### **1. PURPOSE**

The purpose of this guidance is to assist faculty, students and other personnel on the definition of Research versus Quality Assurance/Quality Improvement (QA/QI). In addition, the guidance provides resources to support the development of QA/QI projects. Whenever there is uncertainty as to whether a project is considered to be research or QA/QI, the project leader should request guidance from the WVSOM Institutional Review Board (IRB). **The IRB cannot retroactively approve research.**

It is the responsibility of the project leader who initiates a project to determine if it is research or QA/QI. Research projects must comply with specific policies and regulations designed to protect human subjects and privacy rights. However, it may be difficult for a project leader to determine if his or her project is research or QA/QI. Since this determination may have a significant impact on the project design, procedures, and regulatory compliance, the project leader should not hesitate to ask the IRB for guidance. There are serious consequences for not following WVSOM research policies and procedures and federal regulations when conducting research.

### **2. APPLICABILITY**

This guidance applies to all quality assurance/quality improvement projects undertaken by staff, faculty or students at WVSOM.

### **3. HOW TO USE THIS GUIDE**

The first section provides definitions for Research and Quality Improvement. The second section provides certain characteristics typically associated with research and QI projects. Once you review the definitions and characteristics, you should be able to determine the appropriate category for your project. **If you determine that the project is similar to both definitions, the project is research.**

#### **Section 1. Definitions**

**What is research?** The federal Common Rule defines research as “a systematic investigation including research development, testing and evaluation designed to develop or contribute to generalizable knowledge”. (Source: Code of Federal Regulations 45CFR46.102).

**What is Quality Improvement (QI)?** Quality improvement is defined as “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 the expectations and needs of customers and users of that product. The Institute of Medicine (IOM) defines quality in health care as a direct correlation between the level of improved health services and the desired health outcomes of individuals and populations. Source: Institute of Medicine

**Section 2: Characteristics of Research Projects and Quality Improvement Projects**

<b>Research</b>	<b>Quality Improvement</b>
<p>Research projects must meet IRB requirements for protection of human subjects. Researchers conducting research must also meet HIPAA and FERPA requirements regarding authorization to use or disclose protected health information.</p>	<p>Quality Improvement projects are not covered by IRB requirements. Members of the workforce are allowed by HIPAA to use protected health information for Quality Improvement projects without patient authorization.</p>
<p><b>Characteristics of Research:</b></p> <ul style="list-style-type: none"> <li>• One of the main goals of the project is to advance general knowledge in the academic, scientific, or professional community.</li> <li>• The project will have a specific hypothesis or research question.</li> <li>• The project involves a comprehensive review of relevant literature.</li> <li>• The project will be conducted using a research design that will lead to scientifically valid findings. Elements of a research design include: control groups; random selection of subjects, statistical tests, sample design, etc.</li> <li>• Most of the patients/subjects are not expected to derive a personal benefit from the knowledge gained.</li> <li>• One goal of the project is to generate, evaluate or confirm an expletory theory or conclusion and invite critical appraisal of that conclusion by peers through presentation and debate in public forums.</li> </ul>	<p><b>Characteristics of Quality Improvement:</b></p> <ul style="list-style-type: none"> <li>• The project identifies specific services, protocols, clinical or educational practices, or clinical processes or outcomes within a department, clinical program or facility for improvement.</li> <li>• The project team may review available literature and comparative data, or clinical programs, practices or protocols at other institutions in order to design an improvement plan, but do not plan a full comprehensive literature review.</li> <li>• The project design uses established quality improvement methods (such as DMAIC, PDSA cycle) aimed at producing change within a health center, hospital and/or community setting.</li> <li>• The project design does not include sufficient research design elements to support a scientifically valid finding.</li> <li>• Most of the patients who participate in the project are expected to benefit from the knowledge gained.</li> <li>• The project does not impose any risk or burden to individuals.</li> <li>• The main goal of the project is to improve patient care, clinical care or services, and/or educational processes.</li> </ul>

**4. WORKING ON QUALITY IMPROVEMENT PROJECTS WITH CLINICS, HOSPITALS AND OTHER COMMUNITY ORGANIZATIONS**

Contacting a clinical mentor or faculty member and also the health care provider (clinic, hospital, social-service agency administrator) where you will be completing a QA/QI project is a good

starting point. Health care providers must all meet Health Information and Patient Protection Act (HIPAA) guidelines and may have specific policy and procedure about accessing health care information at their site. They also will discuss HIPAA training requirements if applicable.

## **5. OTHER QUALITY IMPROVEMENT RESOURCES**

<http://www.carnegiefoundation.org/resources/publications/continuous-improvement-education/>

<http://www.ahrq.gov/research/findings/factsheets/quality/qipc/index.html>

<http://www.squire-statement.org>

<http://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/quality-improvement-activities/index.html>

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