WRIGHT STATE UNIVERSITY

QA/QI Guidance
Approved by: Wright State IRB Chair
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QA/QI AND PROGRAM EVALUATION GUIDANCE

The Wright State University Institutional Review Board (IRB) frequently receives inquiries regarding whether projects involving quality improvement, quality assurance/assessment, and/or program evaluation constitutes human subjects' research. Like research, QA/QI activities are generally data driven and involve human participants. Unlike human subjects' research, QA/QI activities generally do not require submission to the IRB for review. However, due to the systematic nature of some QA/QI projects, there may be overlap with research methods and determining whether an activity is QA/QI, research, or both can be challenging.

The purpose of this guidance to:

- Clarify the regulatory requirements associated with quality improvement and program evaluation projects and when they fall under the purview of the IRB
- Clarify for researchers additional HIPAA authorization processes needed

DEFINITION

There is no regulatory definition, but often QA/QI are described as "systematic, data-guided activities" designed to identify specific services, protocols, practices, processes, or outcomes within a department, program or facility for improvement.

Generally QA/QI/Program Evaluation involves:

1. Data collection and analysis for an institution's own internal operation monitoring and program improvement purposes, that is, only if:
    a. the data collection and analysis are limited to the use of data originally collected for any purpose other than the currently proposed activity, or
    b. is obtained through oral or written communications with individuals
2. Implementation of an accepted practice to improve the delivery or quality of care or services (including but not limited to education, training, procedures related to care or services) provided by a specific institution, that is, only if the purposes are limited to:
    a. altering the utilization of the accepted practice; and
    b. collecting data to evaluate the effects on the utilization of the practice

IRB REVIEW NOT REQUIRED

Research, as defined by DHHS at 45CFR46.102(d), means a "systematic investigation", including research development, testing and evaluation, designed to develop or contribute to "generalizable knowledge," such that conclusions will be drawn that can be applied to populations outside of the specific study population.

For IRB purposes, QA/QI/Program evaluation projects are not designed to contribute to generalizable knowledge and does not meet the definition of "research". Thus, IRB review is generally not required.

WHEN QA/QI REQUIRES IRB REVIEW

In some instances, QA/QI activities are designed to accomplish a research purpose, as well as the purpose of improving the quality of care. In such cases, IRB review and approval must be in place BEFORE project initiation.

Examples:

- Activities where data are gathered for improvement of a program, service or healthcare operations AND the results will be generalized across institutions/hospitals/practices should be viewed as research.

- QA/QI activities with the express purpose of prospectively implementing a change in practice, which will later be evaluated through outcomes research, qualifies as human subjects research.
- Prospective collection of identifiable patient or subject- level data for future research is considered human subjects research, regardless of whether the institution that collects the data will de-identify the data before analysis.
- Any study, case report, QA/QI involving an FDA regulated drug/device/biologic requires IRB review. Unlike DHHS regulations, FDA regulations do not provide for exclusion from IRB review when research involves regulated agents.

HIPAA REQUIREMENTS

QA/QI activities, such as looking at outcomes' evaluation or development of clinical guidelines or protocols to support the core functions of treatment and payment of health care activities, may fall under the category of "health care operations" where HIPAA Authorization or Waiver of Authorization may not be necessary. The Privacy Officer/Institutional Research Office and/or committee (i.e. HIRC at Premier Health) can authorize the use of PHI for QA/QI projects that do not require IRB review. In addition, faculty, employees, and students must have appropriate departmental leadership and/or organizational approval/permission before engaging in any form of QA/QI activities.

CHARACTERISTICS OF RESEARCH, AND QA/QI STUDIES CHECK LIST AND CHART

The following check list and chart is intended to help in determining whether a project requires submission to the IRB as a research project involving human subjects. If the project involves some characteristics of a research project, submission to the IRB for review is expected.

Instructions: Answer **YES** or **NO** to each of the following statements about QI projects.	**YES**	**NO**
The aim(s) of the project is to improve the process or delivery of care with established /accepted quality standards, or to implement change according to mandates of the hospital's Clinical Quality Improvement programs. There is no intention of using the data for research purposes.	☐	☐
The specific aim is to improve performance on a specific service or program in the hospital and **is part of usual care.** All participants will receive standard of care.	☐	☐
The project is **NOT** designed to answer a research question or test a hypothesis and is **NOT** intended to develop or contribute to generalizable knowledge.	☐	☐
The project does **NOT** follow a research design (e.g., hypothesis testing or group comparison (randomization, control groups, prospective comparison groups, cross-sectional, case-control)). The project does **NOT** follow a protocol that over-rides clinical decision-making.	☐	☐
The project involves implementation of established and tested quality standards and/or systematic monitoring, assessment or evaluation of the organization to ensure that existing quality standards are being met. The project does **NOT** develop paradigms or untested methods or new untested standards.	☐	☐
The project involves implementation of care practices and interventions that are consensus-based or evidence-based. The project does **NOT** seek to test an intervention that is beyond current science and experience.	☐	☐
The project is conducted by staff where the project will take place, and involves staff who are working at, or patients who are seen at the Partners institution.	☐	☐
The project has **NO** funding from federal agencies or research-focused organizations, and is not receiving funding for implementation research (see External Funding on pg 1).	☐	☐
The clinical practice unit (hospital, clinic, division, or care group) agrees that this is a QI project that will be implemented to improve the process or delivery of care (i.e., not a personal research project that is dependent upon the voluntary participation of your colleagues, students and/or patients).	☐	☐
If there is an intent to, or possibility of publishing your work, you and your Department/QI Oversight group are comfortable with the following statement in your methods section: *"This project was undertaken as a Quality Improvement Initiative at X hospital or clinic, and as such was not formally supervised by the Institutional Review Board per their policies."* **	☐	☐
ANSWER KEY: If the answer to **ALL** of these questions is **YES**, the activity can be considered a Clinical Quality Improvement/Measurement activity that does not meet the definition of research. **IRB review is not required. Keep a dated copy of this checklist in your files.** If the answer to **ANY** of these questions is **NO**, the project must be submitted to the IRB for review.		

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RESEARCH VS QUALITY IMPROVEMENT/PROGRAM EVALUATION ACTIVITIES

If a written determination is required, please complete an IRB application via RSP Gateway.

	RESEARCH **REQUIRES IRB APPLICATION**	**QUALITY IMPROVEMENT/ PROGRAM EVALUATION** **DOES NOT REQUIRE IRB APPLICATION**
INTENT & DESIGN	Intent of project is to contribute to generalizable knowledge; may involve randomization of individuals to different treatments, regimens, or processes (e.g., experimentation with new, novel, untested intervention; testing hypotheses); funding from outside organizations with interest in use of results	Intent of project is to improve, based on existing evidence, a practice or process within a particular institution or ensure it conforms with expected norms; Not designed to develop or contribute to generalizable knowledge; generally does not involve randomization/prospective assignment to different practices or processes
MOTIVATION FOR PROJECT	Project occurs in large part as a result of individual professional goals and requirements; involvement in key project roles of researchers who have no ongoing commitment to improvement of institutional practice	Project occurs regardless of whether individual(s) conducting it may benefit professionally from conducting the project. Authority to impose corrective plan based on outcome of project
MANDATE	Activities not mandated by institution or program	Activity mandated by the institution or clinic as part of its operations
EFFECT ON PROGRAM OR PRACTICE	Findings of the study are not necessarily expected to directly affect institutional or programmatic practice	Findings are expected to directly affect institutional practice and bring about immediate change
POPULATION	Usually involves a subset of individuals - universal participation of an entire clinic, program, or department is not expected, participation is voluntary; generally, statistical justification for sample size used to ensure endpoints can be met.	Requires participation or information on all or most individuals receiving a particular treatment or undergoing a particular practice or process; exclusion of information from some individuals significantly affects conclusions
ANALYSIS	Hold analysis until data collection complete to avoid biasing interpretation of results	Analysis continuous - positive findings immediately implemented. Analysis of data enabled by legitimate access through institutional role.
DISSEMINATION OF RESULTS	Intent to publish or present generally presumed at the outset of project as part of professional expectations, obligations; dissemination of information usually occurs in research/scientific publications; results expected to develop or contribute to generalizable knowledge by filling a gap in scientific knowledge or supporting, refining, or refuting results from other research studies	Intent to publish or present generally not presumed at the outset of the project; dissemination of information often does not occur beyond the institution evaluated; dissemination of information may occur in quality improvement publications; provide benchmarks or base rates rather than to develop or contribute to generalizable knowledge
USE OF CONTROL	Use of placebo and/or control may be planned	Comparison of standard treatments, practices, techniques, processes
DEVIATION FROM STANDARD PRACTICE	May involve significant deviation from standard practice	Unlikely to involve significant deviation from standard practice

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