

RESEARCH VERSUS QUALITY IMPROVEMENT GUIDELINE

PURPOSE

There is often confusion in determining whether Quality Improvement (QI) activities are Research and require review by the Research Committee. This guideline is offered as a tool to help determine if the proposal is research or QI. Whenever there is uncertainty as to whether a proposal is considered research or QI the investigator should request guidance from the Research Committee Chair.

DEFINITIONS

Research: Careful study and investigation, including research development, testing, and evaluation, for the purpose of discovering or contributing to generalizable knowledge.

Quality Improvement Studies: Internal studies related directly to improving or assessing the performance of the institution or its employees or students within the mandate of the institution. Studies are considered to be quality assurance if they involve the systematic monitoring, assessment or evaluation of the various aspects of an organization to ensure that standards of quality are being met, or to correct or enhance the various aspects of the organization. These studies do not seek to establish generalizable knowledge.¹

CHARACTERISTICS OF RESEARCH AND QUALITY IMPROVEMENT

	Research	Quality Improvement
Purpose	To test a hypothesis or to establish clinical practice standards where none are already accepted	To improve performance on a specific service, protocol, clinical practice, process, or outcome within a department, clinical program or facility
Starting Point	To answer a question or test a hypothesis	To improve performance
Design/Methods	Follows a research design (e.g. control groups, random selection of subjects, statistical tests, sample design, etc.) that will lead to scientifically valid findings	Uses established quality improvement methods (e.g. PDSA cycle) aimed at producing change within the Hospital
Benefits	Knowledge sought may or may not benefit current subjects, but may benefit future patients	Knowledge sought directly benefits a process/ program/ service, and may or may not directly benefit patients

¹ THREB. *Application for Retrospective Review of Personal Health Information* (October 2008).

	Research	Quality Improvement
Risks/Burdens	May put subjects at risk	Does not increase risk to patients
Data Collection	Systematic data collection	Systematic data collection
Testing/Analysis	Statistically prove or disprove hypothesis	Compare a program/ process/ service to an established set of standards
End Point	Answer a research question and invite critical appraisal of that conclusion by peers through presentation and debate in public forums	Improve a program/ process/ service at Grand River Hospital

DETERMINING IF A PROJECT IS RESEARCH

Determine if the project meets the definition of research. If unsure, the following questions may guide you. If you determine that the project is similar to both definitions, then the project is research.

Criteria	Yes	No
1. Is the project primarily designed to test a specific hypothesis or answer a specific quantitative or qualitative question?	R	QI
2. Does the project involve a comparison of multiple sites and/or control groups?	R	QI
3. Is the project designed to support generalizations that go beyond the particular population the sample is being drawn from?	R	QI
4. Are patients or providers randomized into different intervention groups in order to enhance confidence in differences that might be obscured by nonrandom selection?	R	QI
5. Does the project impose any additional risks or burdens on participants beyond what would be normally expected or normally experienced during the course of care, program participation or role expectations?	R	QI
6. Is the primary purpose of the project to produce the kind of results that could be published in a research journal?	R	QI
7. Is there funding from an external organization based on support of a "research paradigm" to carry out the proposed activity?	R	QI
8. Does the project seek to test interventions, care practices, or treatments that are not standard (neither consensus-based, nor evidenced-based)?	R	QI
9. Will project participants also likely be among those who might potentially benefit from the result of the project as it proceeds?	QI	R
10. Is the project intended to develop a better practice within Grand River Hospital or your setting?	QI	R

Criteria	Yes	No
11. Would this project still be done at your site even if the results might not be applicable anywhere else?	QI	R
12. Does the language used in the project description refer explicitly to features of a particular program, organization, or locale, rather than using more general terminology such as rural vs. urban populations?	QI	R
13. Is the current project part of a continuous process of gathering or monitoring data within an organization?	QI	R

R = Research

QI = Quality Improvement

What if my project is determined to be QI and I want to publish my experiences?

Intrinsic components of QI are shared learning. It is entirely appropriate to disseminate and replicate QI successes, including through channels that are external to an organization. This may include presentations at meetings and publications in professional journals. Therefore, the mere intent to publish the findings of a QI project does not obligate Research Committee review as long as the publication does not refer to the activity as research and makes it clear the publication is the result of a quality improvement as defined above.

REFERENCES

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- Casarett, D., and Karlawish, J. H. (2000). Determining when quality improvement initiatives should be considered research: proposed criteria and potential implications. *JAMA*, 283(17): 2275-2280.
- Tri-Hospital Research Ethics Board. *Application for Retrospective Review of Personal Health Information*. October 2008.