

Overview of the differences between Quality Improvement and Research

	Research	Quality Improvement
Purpose	To test a hypothesis OR to establish clinical practice standards where none are already accepted	To assess or improve a process, program, or system OR to improve performance as judged by established/accepted standards
Benefits	Knowledge sought may or may not benefit current participants, but may benefit future participants	Knowledge sought directly benefits a process/program/system, and may or may not directly benefit participants
Risks/Burdens	May put participants at risk	Does not increase risk to participants, with exception of possible privacy/confidentiality concerns
Methods	Systematic data collection	Systematic data collection
Analysis	Statistically prove or disprove hypothesis	Compare a program/process/system to an established set of standards, or to establish internal benchmarks
Result	Answer a research question	Improves or creates a program/process/system that results in greater safety, efficiency, or satisfaction

Examples of implementing a practice and collecting patient or provider data for non-research clinical or administrative purposes include:

- A group of affiliated hospitals implements a procedure known to reduce pharmacy prescription error rates, and collects prescription information from medical charts to assess adherence to the procedure and determine whether medication error rates have decreased as expected.
- A clinic increasingly utilized by geriatric patients implements a widely accepted capacity assessment as part of routine standard of care in order to identify patients requiring special services and staff expertise. The clinic expects to audit patient charts in order to see if the assessments are performed with appropriate patients, and will implement additional in-service training of clinic staff regarding the use of the capacity assessment in geriatric patients if it finds that the assessments are not being administered routinely.
- A computer software company is conducting a customer satisfaction survey via the internet to obtain feedback deemed useful when making business decisions for the company. Customers will be sent a link to an anonymous survey and completion of the survey indicates agreement to participate. No personal identifiers will be obtained.

The QI project must be submitted to the IRB if the response to any of the following is “False”:			
1.	The purpose of the project is to improve performance on a specific service or program in the institution and is part of usual care.	True	False
2.	The project involves implementation of established and tested quality standards and/or systematic monitoring, assessment, or evaluation of the institution to ensure existing standards are being met. <i>The project does NOT develop untested methods or new untested standards.</i>	True	False
3.	There is no random assignment of participants to compare outcomes. <i>Randomization implies an experimental approach thus projects using randomization of participants fall into the category of “research”.</i>	True	False
4.	Results will NOT be used to apply knowledge to other programs outside the institution where the project occurs. <i>Application of results to other programs outside the institution implies the intent to contribute to generalizable knowledge.</i>	True	False
5.	The project is NOT subject to peer review (designed to be used outside of the institution). <i>Application of results to other programs outside the institution implies the intent to contribute to generalizable knowledge.</i>	True	False
6.	Anonymity of participants is assured. <i>If participant data includes participant identifiers, anonymity cannot be assured.</i>	True	False
7.	The activities involve no more than minimal risk to participants. <i>Minimal risk is the probability and magnitude of physical or psychological harm that is normally encountered in the daily live, or in the routine medical, dental, or psychological examination of healthy persons.</i>	True	False
8.	If there is an intent to, or possibility of publishing your work, you and your Project Advisor are comfortable with the following statement in your Methods section:	True	False

If you are unsure or need clarification in making the determination of whether your project is Quality Improvement or Research, please contact the IRB at 423-869-6834 or irb@lmunet.edu.