HUMAN RESEARCH PROTECTION

QA/QI activities

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Resource type GUIDANCE

Definitions

Quality Improvement (QI): A working group from the Hastings Center defined QI as: *systematic, data-guided activities designed to bring about immediate improvements in health delivery in particular settings*. Improving the quality of care of patients is a fundamental obligation of health care providers. The QI process involves evaluating and learning from experience.
Research: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.
Systematic Investigation: An activity that is planned in advance and that uses data collection and analysis to answer a question. Although research must include systematic investigation, many non-research activities also include systematic investigation. Systematic investigation does not, in and of itself, define research.

How does QI differ from research?

Both research and quality improvement are systematic investigations that may involve human participants, but they differ in characteristics such as:

Characteristic	Quality Improvement	Human Subjects Research
Purpose	designed to implement knowledge, assess a process or program as judged by established/accepted standards	designed to develop or contribute to generalizable knowledge
Starting Point	knowledge-seeking is integral to ongoing management system for delivering health care	knowledge-seeking is independent of routine care and intended to answer a question or test a hypothesis
Design	adaptive, iterative design	follows a rigid protocol that remains unchanged throughout the research
Benefits	directly benefits a process, system or program; might or might not benefit patients	might or might not benefit current subjects; intended to benefit future patients
Risks	does not increase risk to patients, with exception of possible patients' privacy or confidentiality of data	may put subjects at risk
Participant Obligation	responsibility to participate as component of care	no obligation of individuals to participate
Endpoint	improve a program, process or system	answer a research question
Analysis	compare program, process or system to established standards	statistically prove or disprove hypothesis
Adoption of Results	results rapidly adopted into local care delivery	little urgency to disseminate results quickly
Publication/Presentation	QI practitioners encouraged to share systematic reporting of insights	investigator obliged to share results

Adapted from A Hastings Center Special Report: The Ethics of Using QI Methods to Improve Health Care Quality and Safety

Characteristics unrelated to the requirement for IRB approval

- Intent to publish – both QA/QI and research projects may be published
- Process of data collection – both QA/QI and research projects may include prospective or retrospective data collection and may collect data on living/deceased individuals

Quality improvement presentations/publications

Do not refer to a QA/QI project as ***research*** in presentations or publications—

- If the project was not submitted to the IRB for a determination, the following statement may be included:

  This project was undertaken as a quality assurance/quality improvement initiative and, as such, does not constitute human subjects research and, therefore, not subject to IRB oversight.

- If the IRB provided a determination that the project was considered not to be human subjects research, the following statement can be included in the manuscript:

  This quality assurance/quality improvement initiative was reviewed by the Hennepin Healthcare Institutional Review Board and determined that it does not constitute human subjects research and, therefore, not subject to IRB oversight.

When is IRB approval needed for QI activities?

IRB approval may be required when QI includes some of the following characteristics:

- the activity seeks to develop new knowledge or validate new treatments rather than to assess the implementation of existing knowledge
- when the methodology employs a standard research design, such as randomization
- when the protocol is fixed with a rigid goal, methodology, population, time period, etc.
- when the funding for the activity comes from the outside organizations such as the NIH or those with a commercial interest in the results
- when there will be a delay in the implementation of results
- when the risks from the intervention to participants are greater than minimal

Resource Links

Revised Standards for Quality Improvement Reporting Excellence SQUIRE 2.0 Guidelines
http://squire-statement.org/index.cfm?fuseaction=Page.ViewPage&pageId=471

A Hastings Center Special Report: The Ethics of Using QI Methods to Improve Health Care Quality and Safety
https://www.thehastingscenter.org/uploadedFiles/Publications/Special_Reports/using_qi_methods_to_improve_health_care_quality_safety.pdf

Children's Hospital of Philadelphia (CHOP) IRB website: Quality Improvement vs Research
https://irb.research.chop.edu/quality-improvement-vs-research

Ogrinc, G., Nelson, W.A., Adam, S.M. and O'Hara, A.E. An Instrument to Differentiate between Clinical Research and Quality Improvement. IRB: Ethics & Human Research, Vol. 35, No. 5 (2013): 1-8.
https://pdfs.semanticscholar.org/867c/775353701304f268b83896ed115bb9914095.pdf