

## QUALITY IMPROVEMENT VERSUS RESEARCH IN HEALTH CARE

### Guidance

Most quality improvement efforts do not require IRB review. However, in some cases quality improvement activities are designed to accomplish a research purpose as well as the purpose of improving the quality of care, and in these cases the regulations for the protection of subjects in research (45 CFR part 46) may apply.<sup>1</sup> For example, if a project involves introducing an untested clinical intervention for purposes which include not only improving the quality of care but also collecting information about patient outcomes for the purpose of establishing scientific evidence to determine how well the intervention achieves its intended results, that quality improvement project may also constitute nonexempt human subjects research under the HHS regulations.<sup>1</sup>

Determining whether or not a QI project is research can be one of the most challenging tasks for both researchers and the IRB. Northwell institutional policy allows investigators to assess their own QI projects, and decide if their project does or does not involve research. However institutional policy does not allow employees to conduct research with human subjects without IRB approval. **Therefore it is important to assess your activity appropriately.**

The Northwell IRB can provide a formal determination in writing that your project is (or is not) research requiring IRB review. This is called a Human Subjects Research Determination (HSRD). You can submit the brief HSRD form by following the instructions here:

[www.feinsteininstitute.org/hrpp/submissions](http://www.feinsteininstitute.org/hrpp/submissions).

**It is strongly recommended that you submit a HSRD whenever you are unsure if your project is research.**

### Publication of Quality Improvement Projects

A quality improvement project that is not research **can be published without IRB review/approval**. In the publication, it should be described as a QI initiative, and not as research. For those who submit a HSRD form and receive an IRB determination that the project is not research, this determination can be provided to the journal if they ask for evidence of IRB approval.

A common question is: If I intend to publish my QI project, does the act of publication make it research that needs IRB review? The answer is no - intent to publish is irrelevant in determining whether or not an activity is research.

General Characteristics of QI versus Research (to be used as guidance only; when in doubt submit the HSRD)

Here are some general attributes of Quality Improvement Projects that most likely ARE NOT research:

- Designed to help Northwell comply or meet a recognized, evidence based standard of care.
- Assess the performance of Northwell and compare to national standards.
- Designed to solve a local problem, and the results of the project are expected to produce knowledge that is locally important, but is not generalizable (universally applicable to institutions outside Northwell).
- Uses an iterative design which changes quickly as results come in (i.e. Plan-Do-See-Act Cycle).
- Typically would still be performed even if the project team knew that no professional recognition would result.

Here are some general attributes of Quality Improvement Projects that most likely ARE research needing IRB approval:

- The majority of patients involved are not expected to benefit directly from the knowledge to be gained<sup>2</sup>
- Projects designed to randomize patients to a clinical intervention to assess the safety or efficacy of the intervention
- Multi-center projects which involve collecting data from other national/international sites to create treatment guidelines or other types of generalizable (universally applicable) knowledge
- Projects designed to advance the scientific literature
- Projects designed to advance the clinical care of patients at all hospitals in the United States (not just facilities at Northwell)
- Projects designed to develop new national practice benchmarks<sup>4</sup>
- Typically would NOT be performed if the project team knew that no professional recognition would result.

Here are some examples of Quality Improvement Projects that are **NOT** research:

- A radiology clinic uses a database to help monitor and forecast radiation dosimetry. This practice has been demonstrated to reduce over-exposure incidents in patients having multiple procedures. Patient data are collected from medical records and entered into the database. The database is later analyzed to determine if over-exposures have decreased as expected.
- 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.
- The staff of an adult oncology clinic cares for patients receiving chemotherapy that commonly causes severe mucositis. The staff members implement a widely accepted oral care assessment tool as part of routine standard of care. An evidence-based training program on how to use the oral assessment tool is provided to the patient care team. A chart review a month later is used to evaluate whether a change in practice has occurred, measured by the number of oral care assessments performed and whether these assessments were performed with appropriate patients.<sup>3</sup>
- A graduate student project will evaluate the effect of standardizing care for patients presenting to the Emergency Room with diabetic ketoacidosis using the evidence-based guideline published by the American Diabetes Association. A SUNRISE search identifies patients admitted for diabetic ketoacidosis a year before the evidence-based care guideline was implemented and also for patients treated a year later in compliance with the guideline. Outcome measures include provider guideline adherence as well as clinically specific indicators that measure timely and efficient reversal of ketoacidosis.<sup>3</sup>

<sup>1</sup>OHRP FAQs : <http://www.hhs.gov/ohrp/policy/faq/quality-improvement-activities/view-quality-improvement-activities.html>

<sup>2</sup>Determining When Quality Improvement Initiatives Should Be Considered Research: Proposed Criteria and Potential Implications. JAMA, May, 2000 – Vol 283, No. 17. Authors: Casarett, Karlawish, and Sugarman.

<sup>3</sup>Adapted with permission from Duke University Health System, [https://irb.duhs.duke.edu/sites/irb.duhs.duke.edu/files/QI\\_policy\\_and\\_checklist\\_4-30-2013jw.pdf](https://irb.duhs.duke.edu/sites/irb.duhs.duke.edu/files/QI_policy_and_checklist_4-30-2013jw.pdf)

<sup>4</sup>Asher, Anthony L. MD, McGirt, MJ MD, Glassman, SD MD, Groman, R, MPH, Resnick, DK, MD, MS, Mehrlich, M, RN, BSN, Spivey, E, BS, and McCormick, P, MD, MPH. (2013) Regulatory considerations for prospective patient care registries: lessons learned from the National Neurosurgery Quality and Outcomes Database. Neurosurg Focus, 34(1). 1-9.