Quality Improvement (QI) and Program Evaluation (PE)

There is no regulatory definition for Quality Improvement (QI) or Program Evaluation (PE), but they are often described as being designed to bring about immediate (or nearly immediate) improvements in delivery or system performance. These activities include changes to systems or processes, development of guidelines, training and education, and access to private information. The goal of these activities is to provide real-time evidence-based data related to performance, needs, or output.

Many activities generally do not require review by an IRB because they do not meet the definition of research (45CFR46.102.e). Research is a “systematic investigation including research development, testing and evaluation designed to develop or contribute to generalizable knowledge.” QI or PE activities may be systematic in nature; however, many are not designed to develop or contribute to generalizable knowledge even though the information may be shared throughout the organization.

What are some examples of QI/PE?

- Ensuring new evidence-based interventions are incorporated into practice
- Improvement of over-all quality of life
- Reduction of morbidity and mortality
- Ensuring that patients receive evidence-based interventions for their particular illness
- Improvement in patient and family comprehension
- Reduction in in-patient admissions and length of stay
- Reduction of ER visits
- Reduction in costs of service
- Evaluating procedures no greater than minimal risk to patients,
- Usual care practices, and
- Interventions offered to all patients.

Differences between QI/PE and research

<table>
<thead>
<tr>
<th>Points to consider</th>
<th>Research</th>
<th>QI/PE</th>
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<tbody>
<tr>
<td>Purpose</td>
<td>To test a hypothesis OR establish clinical practice standards where none are accepted</td>
<td>To assess or promptly improve a process, program, or system; OR improve performance as judged by accepted/established standards</td>
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<tr>
<td>Starting Point</td>
<td>To answer a question or test a hypothesis</td>
<td>To improve performance</td>
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<td>Benefits</td>
<td>Designed to contribute to generalizable knowledge and may or may not benefit subjects</td>
<td>Designed to promptly benefit a process, program, or system and may or may not benefit patients or clients</td>
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<td>Risks/Burdens</td>
<td>May place a subject at risk</td>
<td>Be design, does not increase risk</td>
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<td>Data Collection</td>
<td>Systematic data collection</td>
<td>Systematic data collection</td>
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<tr>
<td>End Point</td>
<td>Answer a research question</td>
<td>Promptly improve a program/process/system</td>
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<tr>
<td>Testing/Analysis</td>
<td>Statistically prove or disprove a hypothesis</td>
<td>Compare to an established set of standards</td>
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Can a project be both QI/PE and human research?
Yes, projects can be both QI/PE and human research. The following characteristics make it more likely that a project involves both QI/PE and research. Consult with the IRB if you are uncertain.

- Randomization of patients into different intervention groups in order to enhance confidence in differences that might be obscured by nonrandom selection (but not to achieve equitable allocation of a scarce resource).
- Testing issues that are beyond current science and experience, such as new treatments.
- The involvement in key project roles of researchers who have no ongoing commitment to improvement of the local care situation.
- Delayed or ineffective feedback of data, especially if feedback is delayed or altered in order to avoid biasing the interpretation of results.
- Funding from an outside research organization with an interest in the use of the results.
- Secondary analysis of identifiable QI or PE data with the intent to develop or contribute to generalizable knowledge is research and requires human subjects review.

If a study includes randomization, is it always considered HSR?
No, however, randomization is a trigger that the project should be discussed with the HSPP. An example of a QA/QI study that involved medication compliance included the randomization of patients to one of three conditions:

- In one condition patients were given a cell phone and a reminder call when it was time to take their medication.
- Patients in a second condition were given a reminder call but no cell phone.
- Patients in a third condition took their medication while being directly observed by staff (direct observation therapy--DOT).

Is it research if I intend to publish?
The intent to publish is an ‘insufficient criterion’ for determining whether a quality improvement activity involves research, according to OHRP. When QI/PE is published or presented, the intent is usually to discuss potentially effective models, strategies, assessment tools or to provide benchmarks, rather than to develop or contribute to ‘generalizable’ knowledge.

What if I need to access PHI?
HIPAA makes an exception for QI/PE activities, including outcomes evaluation and development of clinical guidelines or protocols. These activities fall under the category of ‘health care operations’ for which no HIPAA Authorization or Waiver of Authorization needs to be sought. The organization that owns the medical information must grant permission to access it for QI/PI.

The UA requires that any access to health information in an electronic medical record,
regardless if it is human research, be submitted to the IRB for review. The 'Determination of Human Research' form should be used to document access to this private information for tracking purposes.