Research vs. Quality Improvement/Quality Assurance

OVERVIEW
Research activities and QI/QA activities both involve the collection of information. The purpose of this guidance is to assist in determining when an activity involving patients represent quality improvement/quality assurance (QI/QA) and when an activity meets the definition of human subjects research (HSR). The distinction is important, because QI/QA projects do not require IRB review and approval, whereas all HSR projects do.

DEFINITIONS
Research: A systematic investigation, including development, testing and/or evaluation, designed to develop or contribute to generalizable knowledge.

Quality Improvement/Quality Assurance (QI/QA): Activities undertaken to measure the effectiveness of a process, program or service, and the results of the activity will only be shared with individuals associated with the process, program or service being evaluated.

ACTIVITY DISTINCTION

<table>
<thead>
<tr>
<th>Requires IRB Review</th>
<th>Does NOT Require IRB Review</th>
</tr>
</thead>
<tbody>
<tr>
<td>• The results of the activities are to establish scientific evidence and contribute to generalizable knowledge.</td>
<td>• The results of the activities are to be shared with individuals associated with the process, program or service being evaluated.</td>
</tr>
</tbody>
</table>

Example:
Evaluations to test a new, modified, or previously untested intervention, service or program to determine whether it is effective and can be used elsewhere.

Examples:
Evaluations of a specific project, process, etc. where the primary intent of the activity is solely for internal assessment or improvement.

Evaluations to assess the success of an established program in achieving its objective and the information gained from the evaluation will be used to provide feedback to improve the program. The evaluation serves a management tool for monitoring and improving the program.

Given that QI/QA initiatives often have the goal of generating knowledge that will guide improvements in limited settings (e.g. clinical departments, health care delivery programs, classroom curriculums) it may be difficult at the start of such activities to determine whether knowledge acquired as a result of a QI/QA initiatives is “generalizable” or will become “generalizable.” The HRPP recognizes this difficulty and strongly encourages those involved in QI/QA activities to contact the HRPP Office to determine if a project needs to be reviewed by the IRB.

REFERENCES
OHRP’s Quality Improvement Activities FAQ