

## Quality Improvement/Program Evaluation vs. Research

*Adapted from "CHOP Screening Checklist for Quality Improvement (QI) Projects".*

This checklist will help you assess whether a proposed project is QI/PE or potentially human subjects research. If all of the check marks are inside the **shaded gray boxes**, then the project is very likely QI/PE and not human subjects research. Projects that are not human subjects research do not fall under the IRB's purview, but still need to be submitted for a determination as such.

Please complete an intake form via WRG, making sure that for Q.6 you are selecting **"f. Human Subjects Research Determination Request"**, as the application type.

Consideration	Question	Yes ✓	No ✓
<b>PURPOSE</b>	Is the primary aim or motive of the project either to: <ul style="list-style-type: none"> <li>Improve care/processes <b>right now?</b></li> <li><b>OR</b></li> <li>Improve operations, processes, or efficiency?</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>
<b>RATIONALE</b>	Is there sufficient evidence for, or acceptance of, this mode or approach to support implementing this activity or to create practice change, based on: <ul style="list-style-type: none"> <li>literature,</li> <li>consensus statements, or</li> <li>consensus among clinician team?</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>
<b>METHODS 1</b>	Are the proposed methods flexible and customizable, and do they incorporate rapid evaluation, feedback and incremental changes?	<input type="checkbox"/>	<input type="checkbox"/>
<b>METHODS 2</b>	Do the methods include any of the following? <ul style="list-style-type: none"> <li>Control group</li> <li>Randomization</li> <li>Fixed protocol</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>
<b>RISK</b>	Is the risk related to the project minimal and no more than usual care or practices (including the unavoidable minimal risk in implementing any changes made in processes of care)?	<input type="checkbox"/>	<input type="checkbox"/>
<b>PARTICIPANTS</b>	Will the activity only involve participants (patients, parents, students, or staff) who are ordinarily seen, cared for, or work in the setting where the activity will take place?	<input type="checkbox"/>	<input type="checkbox"/>
<b>FUNDING</b>	Is the project funded by any of the following? <ul style="list-style-type: none"> <li>An outside organization with an interest in the results</li> <li>A manufacturer with an interest in the outcome of the project relevant to its products</li> <li>A non-profit foundation that typically funds research, or by internal research accounts</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>

If you have any questions about this topic, or need further information, please click on the button below to submit a consultation request:

