

## CHOP Screening Checklist for Quality Improvement (QI) Projects

This checklist will help you determine whether a proposed project is in fact QI or potentially human subjects research.

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 <b>right now</b> for the next patient seen?</li> <li style="text-align: center;"><b>OR</b></li> <li>• Improve operations or efficiency?</li> </ul>		
<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>		
<b>METHODS 1</b>	Are the proposed methods flexible and customizable, and do they incorporate rapid evaluation, feedback and incremental changes?		
<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>		
<b>RISK</b>	Is the risk related to the project minimal and no more than usual care (including the unavoidable minimal risk in implementing any changes made in processes of care)?		
<b>PARTICIPANTS</b>	Will the activity only involve participants (patients, parents, or CHOP staff) who are ordinarily seen, cared for, or work in the setting where the activity will take place?		
<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>		
<p>If all of the check marks are inside the shaded gray boxes, then the project is very likely QI and not human subjects research. Projects that are not human subjects research do not need review by the IRB.</p> <p>For more guidance about whether the activity meets the definition of Human Subjects Research see <a href="https://irb.research.chop.edu/not-human-subjects-research">https://irb.research.chop.edu/not-human-subjects-research</a></p>			

**Characteristics of a QI project that do not determine the need for IRB Review:**

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

**Clarifications for publishing QI work:**

- Do not refer to QI projects as research in publications or presentations.
- If the project was not submitted to the IRB for determination, the following statement may be included in the manuscript:  
*“This project was undertaken as a Quality Improvement Initiative and as such does not constitute human subjects research.”*
- If the project was reviewed by the IRB and was determined not to be human subjects research, the following statement can be included in the manuscript:  
*“This Quality Improvement Initiative was reviewed and determined to not meet the criteria for human subjects research by the Children’s Hospital of Philadelphia Institutional Review Board.”*

**Resource Links:**

- [Revised Standards for Quality Improvement Reporting Excellence SQUIRE 2.0 Guidelines](#)
- [A Hastings Center Special Report: The Ethics of Using QI Methods to Improve Health Care Quality and Safety](#)
- [CHOP IRB Website: 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.](#)