

**IRB EQUIP TIPS**

**Quality Improvement (QI) Research vs. QI Projects**

V 4.1 August 2022

**Quality Improvement (QI) Project vs QI Research**

Both QI Projects and QI research are systematic investigations that may involve human participants, but they differ in important ways:

	<b>QI Human Subjects Research</b>	<b>Quality Improvement Project</b>
<b>Purpose</b>	<ul style="list-style-type: none"> <li>designed to develop or contribute to <b>generalizable knowledge</b> (e.g., UCI master thesis or dissertation)</li> <li><b>develop new knowledge</b> or validate new treatments</li> </ul>	designed to <b>implement knowledge, assess</b> a process or program as judged by established / accepted standards
<b>Starting Point</b>	knowledge-seeking is independent of routine care and intended to answer a question or test a hypothesis	knowledge-seeking is integral to ongoing current practices / management system for delivering health care
<b>Design</b>	follows a rigid protocol that remains unchanged throughout the research (e.g., <b>randomization</b> )	adaptive, iterative design
<b>Risks</b>	may put subjects at risk	does not increase risk to patients, with exception of possible patients' privacy or confidentiality of data
<b>Endpoint</b>	<b>answer a research question</b>	<b>improve an institutional program, process or system</b>
<b>Analysis</b>	<b>statistically prove or disprove hypothesis</b>	<b>compare program, process or system to established standards</b>
<b>Adoption of Results</b>	little urgency to disseminate results quickly	results rapidly adopted into local current practices / care delivery
<b>Publication/ Presentation</b>	<ul style="list-style-type: none"> <li>Investigator obliged to share results.</li> <li>For QI Research that qualifies for <b>Exempt Self-Determination</b>, you may include the following statement in your manuscript:   <i>"This Quality Improvement Research Project was <u>determined by the Investigator</u> to be Exempt under exemption category(ies) &lt;add&gt;."</i> </li> </ul>	<ul style="list-style-type: none"> <li>QI practitioners encouraged to share systematic reporting of insights</li> <li>A "QI Project" can be published without prior IRB approval. You may include the following statement in your manuscript:   <i>"This project was undertaken as a Quality Improvement Initiative and as such does not constitute human subjects research."</i> </li> </ul>
<b>Ethical Oversight</b>	<ul style="list-style-type: none"> <li><b>IRB</b> provides ethical oversight for QI research requiring IRB review and approval (<b>Exempt, Expedited</b>).</li> <li><b>Departments / Divisions</b> provide ethical oversight for QI Research that DOES NOT require IRB Review (<b>Exempt Self-Determination</b>).</li> </ul>	<ul style="list-style-type: none"> <li><b>Departments and divisions</b> provide ethical oversight of <b>QI Projects</b> to determine: <ul style="list-style-type: none"> <li>The risks to participants are not greater than minimal.</li> <li>There are appropriate protections for privacy &amp; confidentiality in place.</li> </ul> </li> </ul>

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#### Resource Links:

- [UCI Exempt Self-Determination Process Letter](#)
- [OHRP: 2018 Exempt Review Categories](#)
- [OHRP: Expedited Review Categories](#)
- [UCI IRB Guidance – Do You Need IRB Review?](#)
- [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.](#)