**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:

<table>
<thead>
<tr>
<th>Purpose</th>
<th>QI Human Subjects Research</th>
<th>Quality Improvement Project</th>
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|         | • designed to develop or contribute to **generalizable knowledge** (e.g., UCI master thesis or dissertation)  
         | • **develop new knowledge** or validate new treatments | designed to **implement knowledge, assess**  
         | | a process or program as judged by  
         | | established / accepted standards |

| Starting Point | 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 |
| Design | follows a rigid protocol that remains unchanged throughout the research (e.g., **randomization**) | adaptive, iterative design |
| Risks | may put subjects at risk | does not increase risk to patients, with exception of possible patients' privacy or confidentiality of data |
| Endpoint | answer a research question | improve an institutional program, process or system |
| Analysis | statistically prove or disprove hypothesis | compare program, process or system to established standards |
| Adoption of Results | little urgency to disseminate results quickly | results rapidly adopted into local current practices / care delivery |
| Publication/Presentation | • Investigator obliged to share results.  
• For QI Research that qualifies for **Exempt Self-Determination**, you may include the following statement in your manuscript:  
   “This Quality Improvement Research Project was **determined by the Investigator** to be **Exempt under exemption category(ies) <add>**.” | • QI practitioners encouraged to share systematic reporting of insights  
• A “QI Project” can be published without prior IRB approval. You may include the following statement in your manuscript:  
   “This project was undertaken as a Quality Improvement Initiative and as such does not constitute human subjects research.” |
| Ethical Oversight | • IRB provides ethical oversight for QI research requiring IRB review and approval (**Exempt, Expedited**).  
• **Departments / Divisions** provide ethical oversight for QI Research that DOES NOT require IRB Review (**Exempt Self-Determination**). | • **Departments and divisions** provide ethical oversight of **QI Projects** to determine:  
   o The risks to participants are not greater than minimal.  
   o There are appropriate protections for privacy & confidentiality in place. |

**The QI guidance was adapted from Children’s Hospital of Philadelphia IRB – we thank the CHOP IRB**
IRB EQUIP TIPS
Quality Improvement (QI) Research vs. QI Projects
V 4.1 August 2022

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