

IRB EQUIP TIPS

Quality Improvement (QI) Research vs. QI Projects

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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:

	QI Human Subjects Research	Quality Improvement Project
Purpose	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Investigator obliged to share results. For QI Research that qualifies for Exempt Self-Determination, 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) <add>."</i> 	<ul style="list-style-type: none"> 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: <i>"This project was undertaken as a Quality Improvement Initiative and as such does not constitute human subjects research."</i>
Ethical Oversight	<ul style="list-style-type: none"> 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). 	<ul style="list-style-type: none"> Departments and divisions provide ethical oversight of QI Projects to determine: <ul style="list-style-type: none"> The risks to participants are not greater than minimal. 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****

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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.](#)