Title: Quality Improvement (QI) *Project* vs Quality Improvement (QI) *Research*
Date of Last Revision: 05/28/19, 07/19/19
Audience: Researchers
Citation: https://escholarship.org/uc/item/5jk5z110

	QI PROJECT	QI RESEARCH
DEFINITION	An activity that is ***specifically initiated*** with a ***goal of improving*** the performance of ***institutional practices*** *in relationship to an established standard* However, if a project was originally initiated as a local QI project *but the findings are of interest and the project investigator chooses to expand the findings into a research study*, IRB review would be required at that time	An activity that is ***initiated*** with a ***goal of improving the performance of institutional practices*** *in relationship to an established standard*, with the ***intent*** to ***contribute to generalizable knowledge*** *("widely applicable")* Meets the definition of ***Human Subjects Research***: ▪ Human Subjects ▪ Research
CORE ELEMENTS	**HIPAA Rule:** the following activities are considered "*healthcare operations*" (they are *not* considered "research"): ▪ Conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines, if the obtaining of generalizable knowledge is not the primary purpose of studies resulting from the activities ▪ Population-based activities relating to improving health or reducing healthcare costs ▪ [Clinical] protocol development, case management and care coordination **Authorization:** - HIPAA Rule does *not* require a covered entity to secure individual authorization (nor a waiver) for *use or disclosure* of *PHI* for these activities, *as long as the covered entity describes the activities* in its *Notice of Privacy Practices* - HIPAA Authorization is *required* if there is *disclosure of PHI outside of the covered entity* • *"Release to"* section: *UCI faculty/resident name*	**Intent:** *generate* ***generalizable*** *results* **Additional risk or burden:** the project *includes risks or burdens beyond the standard of practice* to make the results generalizable **Design:** involves *randomization or an element that may be considered less (or more) than standard of care* **HIPAA Rule:** requirements for waiving informed consent and/or waiving the requirements for documentation of informed consent must be met

	• *"Purpose"* section: *QI activity publication* • the signed authorization should be uploaded and maintained in the patient's record; note, the patient has the right to ask for a copy of the signed authorization form • translated HIPAA Authorizations **Privacy and confidentiality:** a QI activity retains the standard for ensuring the privacy and confidentiality of the population and data being accessed and studied; also, *review the above note regarding HIPAA Authorization*	
Documentation	**Documentation:** ▪ journals and conference platforms typically ask whether your project received an IRB review ▪ recommendation: submission of a NHSR form (return to the IRB, and the IRB will complete this form and return to you), and maintain the final signed form for the life of the project - Submit a Request for *Determination of Non-Human Subject Research* form (*NHSR*) **Publication:** ▪ publications must describe the activity as a *"project"* ; also, *review the above note regarding HIPAA Authorization*	**IRB review:** activities that meet the definition of *Human Subjects Research* require IRB review ▪ How to apply
Resources	▪ 45 CFR 46.102(e)(1): Federal Policy's definition of Human Subject (v 2018) ▪ 45 CFR 46.102(l): Federal Policy's definition of Research (v 2018) ▪ 45 CFR 46 (v 2018): Preamble for Quality Improvement Activities ▪ IRB Ethics & Human Research, Vol 39(3), May-June 2017, Pages 1-10 ▪ Journal of Empirical Research on Human Research Ethics, 2015, Vol 10(2), Pages 209-210 ▪ 45 CFR 164.506 (2013): Definition of Health Care Operations ▪ IRB Ethics & Human Research, Vol 35(5), September-October 2013, Pages 1-8 ▪ Research Compliance Professional's Handbook, 2nd Edition, 2013, Chapter 8, Page 79. ▪ OHRP Quality Improvement Activities FAQ (2010) ▪ Institutional Review Board, Management and Function, 2nd Edition, 2006, Chapter 4-3, Pages 102-103. ▪ 2005 California Senate Bill 13 (SB 13) (*when applicable) ▪ Example of a published *QI **Project***	