

Yale Human Research Protection Program

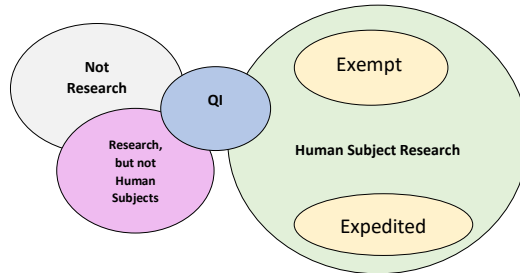
Reference Guide – Quality Improvement Projects

Purpose

This document provides guidance regarding how to determine whether a proposed project meets the definition of Quality Improvement or Human Subjects Research.

Background

The distinction between Quality Improvement and Human Subjects Research is not always clear. Attributes, such as publication of findings, methodology, or systematic collection of data, do not necessarily differentiate human subjects research from Quality Improvement activities because these attributes can be shared by both.



Adopted from Children's Hospital of Philadelphia website See, <https://irb.research.chop.edu>.

Quality Improvement (QI)

- Quality Improvement projects involve systematic, data-guided initiatives or processes designed to improve clinical care, patient safety, health care operations, services, and programs or to develop new programs or services (e.g., teaching evaluations, patient/employee service surveys). QI is intended to use experience to identify effective methods, implement the methods broadly, and evaluate the immediate impact or effect of the implemented changes. As such, QI is an intrinsic part of good clinical practice where lessons learned are used to enhance future healthcare delivery for patients, healthcare operations and services or programs at the institution in which the QI activity is implemented.
- A QI project may involve implementing a practice (for example, to improve the quality of patient care or collecting and immediately assessing data regarding the degree to which implementation of the practice was successful for clinical, practical, or administrative purposes). Process-based QI activities strive to overcome barriers to dissemination and implementation of best practices. These “best practices” represent accepted, evidence-based approaches to caring for patients (such as hand-washing, ordering mammograms for eligible women, or improving glucose control in diabetic patients), enhancing the work environment for more efficient practices by the employee rather than experimental or unproven interventions.

Human Subjects Research (HSR)

- Research: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.
- Clinical Investigation (FDA): Any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the FDA or the results of which are intended to be submitted later to, or held for inspection by, the FDA as part of an application for a research or marketing permit.
- Human Subject (OHRP): A living individual about whom an investigator (whether professional or student) conducting research: (1) Obtains information or biospecimens through intervention or interaction with the individual, and uses studies, or analyzes the information or biospecimens; or (2) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.
- Human Subject (FDA, non-device): Human subject means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient.
- Human Subject (FDA – Device): A human who participates in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control. A subject may be healthy or have a medical condition or disease.

For additional information see Appendix A and Bⁱ.

QUALITY IMPROVEMENT REVIEW REQUIREMENTS

1	No Further Review is Generally Required <i>unless Required by your Department</i>	A QI project that does not meet the definition of human subjects research and the conditions set forth in 2. below do not exist.
2	Further Review Generally is Required Nursing Projects: Contact NursingScientificReviewComm@YNH.ORG Other Projects: Contact gina.larsen@yale.edu , or cathleen.montano@yale.edu	<ul style="list-style-type: none"> • An authoritative determination is required by departmental policy • As a condition of a training program; by a journal or conference prior to acceptance of a health care-related manuscript for publication or presentation • You are receiving external non-research funding from external sources other than federal funding or funding from a research focused organization. • The project involves sensitive content that targets vulnerable populations (such as faculty, staff, students, trainees, children, pregnant women, prisoners, active military personnel, individuals with impaired decision making, etc.); or if you are unsure whether the project is QI or HSR.
3	Submission to the IRB Required	A QI/Other project that meets the definition of Human Subjects Research

Appendix A: Human Subjects Research versus Quality Improvement

For each statement in each row, choose only one answer in each column. Leave the item blank if neither choice applies.

	Human Subjects Research	Yes (✓)	Quality Improvement	YES (✓)
1. Purpose / Intent	<input type="checkbox"/> Designed to develop or contribute to generalizable knowledge		<input type="checkbox"/> Designed to implement knowledge, assess a process, program, or system as judged by established/accepted standards	
	<input type="checkbox"/> Identifies a specific deficit in scientific knowledge from the literature		<input type="checkbox"/> Describes the nature and severity of a specific local performance gap	
	<input type="checkbox"/> Proposes to address or identify specific hypotheses in order to develop knowledge or advance existing knowledge		<input type="checkbox"/> Focus is to improve a specific aspect of health or health care delivery that is currently NOT consistently and appropriately being implemented at this site	
	<input type="checkbox"/> Knowledge-seeking is independent of routine care and intended to answer a question or test a hypothesis		<input type="checkbox"/> Knowledge-seeking is integral to ongoing management system for delivering health care	
2. Design / Methods	<input type="checkbox"/> Specific protocol defines the intervention, interaction, and use of collected data and tissues plus project may rely on the randomization of individuals to enhance confidence in differences		<input type="checkbox"/> Adaptive, iterative design; mechanisms of the intervention are expected to change over time (i.e., an iterative activity) in response to ongoing feedback	
	<input type="checkbox"/> May use qualitative or quantitative methods to make observations, make comparisons between groups, or generate hypotheses		<input type="checkbox"/> Plan for intervention and analysis includes an assessment of the system (i.e., process flow diagram, fishbone, etc.)	
	<input type="checkbox"/> Statistical methods primarily compare differences between groups or correlate observed differences with known health outcomes		<input type="checkbox"/> Statistical methods evaluate system level processes and outcomes over time with statistical process control or other methods	
3. Funding	<input type="checkbox"/> External funding (federal agencies / research focused organizations / funding for implementation research)		<input type="checkbox"/> No external funding OR only non-research grant funding	
4. Location	<input type="checkbox"/> More than one institution (outside of YNHHS/Yale/Agent of Yale) involved in the project		<input type="checkbox"/> No other institution involved in the project (occurring at YNHHS, Yale University, or location under the purview of, or acting as Yale agent)	
5. Benefits	<input type="checkbox"/> Might or might not benefit current subjects; intended to benefit future patients		<input type="checkbox"/> Directly benefits a process, system, or program; might or might not benefit patients	
	<input type="checkbox"/> Intervention, interaction, or use of identifiable private information occurs outside of the usual clinician-patient therapeutic relationship		<input type="checkbox"/> Intervention would be considered within the usual clinician-patient therapeutic relationship	
	<input type="checkbox"/> Direct benefit to each individual participant or for the institution is not typically the intent or is not certain		<input type="checkbox"/> Direct benefit to participants is indicated (e.g., for the decrease in risk by receiving a vaccination/creating a safer hospital system)	
	<input type="checkbox"/> Potential societal benefit in developing new or advancing existing generalizable knowledge		<input type="checkbox"/> Potential local institutional benefit is specified (e.g., increased efficiency or decreased cost)	
5. Risks	<input type="checkbox"/> May put participants at risk separate from the care they are receiving, which may include physical, emotional, social, financial, legal, risk to provider license, mandatory reporting, as well as risk to privacy or the confidentiality of health information from participation in the project		<input type="checkbox"/> Risk to the participants no greater than what is involved in the care they are already receiving.	
7. Participants / Consent	<input type="checkbox"/> No obligation of individuals to participate; project requires voluntary informed consent for interventions that are not part of standard clinical care and for access, use or disclosure of their protected health information that is not part of usual treatment, payment and operations		<input type="checkbox"/> Participation as a component of care; consent that is normally sought in clinical practice as an activity considered part of the usual care	
8. Endpoint	<input type="checkbox"/> Answers a research question		<input type="checkbox"/> Improve a program, process, or system	
9. Results	<input type="checkbox"/> Generally must wait until entire project is completed before disseminating results; little urgency to disseminate quickly		<input type="checkbox"/> Results rapidly adopted into local care delivery	
	<input type="checkbox"/> Results and analysis may be delayed or periodic throughout the duration of the project, except to protect patient safety; results will primarily be used to inform further investigations, but may be implemented directly into clinical practice		<input type="checkbox"/> Implementation is immediate so that the review of results occurs throughout the process and may be used for next QI activity	
	<input type="checkbox"/> Results are intended to generalize beyond the study population		<input type="checkbox"/> Extrapolation of results to other settings is possible, but not the main intent of the activity	
10. Publication / Sharing	<input type="checkbox"/> Investigator obliged to share results; it is expected that the results will be published or presented to others through a peer-reviewed process		<input type="checkbox"/> QI practitioners encouraged to share systematic reporting of insights, as long as it is not referred to as research; system level outcomes, processes, refinement of the intervention, and the applicability of the intervention in specific settings/contexts may be shared through peer-reviewed publication and presentation outside of the institution	

Appendix B

Examples – Human Subjects Research versus Quality Improvement

CASE	HSR or QI that requires review	QI	NOTES
Testing a novel alert in electronic medical record system to notify care providers when patients with a potential cardiac arrest present to the Emergency Department to allow for a fast-tracked triage; the rates of mortality of patients with cardiac arrest waiting in ED will be measured to study effectiveness of this alert system	X		The intervention is novel, the purpose of the activity is to test effectiveness of the intervention. Risk may be greater than minimal to those patients whose symptoms are not caught by the alert but who otherwise would be triaged faster to receive care.
Using existing data or residual, clinically-required specimen <i>to validate</i> an internal, established, or standard method of care		X	Individuals are confirming or evaluating an existing practice.
Using existing data or residual, clinically-required specimen <i>in order to</i> establish a standard method of care	X		Individuals are seeking to develop or establish a new practice.
Collecting extra, non-clinically required specimens or data through an intervention that could lead to an increased risk to patients from the same interventions performed for clinical reasons e.g., asking patient to undergo an extra x-ray for a QI project on software calibration, asking for extra blood sample	X		Collection of non-standard or non-clinical data or samples may be necessary to accomplish a QI project. If the collection could lead to increased risks either when combined with clinical procedure (e.g., there is a limit on volume of blood that can be safely drawn) or when the procedure on its own presents risks (risk of radiation), the IRB must review the project. In contrast, asking patients to donate additional fecal or urine sample for a QI project would not require IRB review.
A survey to evaluate an internal, established program; the main purpose of this survey is to improve local established program		X	Evaluation of an internal process for the purpose of process program improvement typically does not meet the regulatory definitions of Research
A confidential survey of minors regarding their sexual and gender identification development, history of suicidal ideation, and the youth’s opinions about the clinicians’ approach to this area of their health; the main purpose of the survey is to assess whether the hospital should implement a mandatory staff training on care of LGBTQIA youth in clinical setting	X		The survey to assess a need for training is most likely a QI project. Due to the sensitive nature of the questions and possible incidental findings (risk of suicide), IRB review is required to assess potential risk to participants and need for any follow-up activities to ensure safety of the individuals completing the survey.
Project to improve knowledge of and compliance with existing hand hygiene practices among clinicians in a hospital setting; anonymous pre and post survey is conducted along with a medical record review to assess the rate of infections among patients.		X	The purpose of this project is to implement a practice to improve the quality of care. The data are collected to track/monitor/confirm the results of that implementation.
Project to evaluate the effectiveness of novel hand hygiene intervention in a hospital setting; anonymous pre and post survey is conducted along with a medical record review to assess the rate of infections among patients	X		The main purpose of this project is to examine the effectiveness of a new practice to improve the quality of care. The regulations for human subjects research apply and IRB review is required.
Project to assess provider knowledge regarding hand hygiene practices; survey data will be collected along with individual HR data to correlate years of practice and education with the levels of knowledge and attitude toward importance of hand hygiene	X		The survey to assess a need for training is most likely a QI project. Results of the project may have impacts to reputation or employability of the clinicians completing the survey. IRB review will be required to assess the risks to participants.
Evaluation of characteristics of patients with catheter-associated UTIs on a particular service		X	See, https://www.partners.org/Assets/Documents/Medical-Research/Clinical-Research/Clinical-QI-Checklist.doc
Implementation of a validated daily checklist to routinely assess “extubation readiness” in an ICU		X	See, https://www.partners.org/Assets/Documents/Medical-Research/Clinical-Research/Clinical-QI-Checklist.doc
Examination of “no-shows” at a clinic in order to ensure linkage to care and cost-effective utilization of staff time; this could include calling patients to ascertain why they did not make a scheduled visit		X	See, https://www.partners.org/Assets/Documents/Medical-Research/Clinical-Research/Clinical-QI-Checklist.doc
Tracking “Door-to-Procedure” or “Door-to-Drug” turnaround times to develop ways to better meet accepted standards or goals		X	See, https://www.partners.org/Assets/Documents/Medical-Research/Clinical-Research/Clinical-QI-Checklist.doc
Monitoring radiation dosimetry in order to minimize radiation exposure in young patients likely to undergo multiple scans for care		X	See, https://www.partners.org/Assets/Documents/Medical-Research/Clinical-Research/Clinical-QI-Checklist.doc
Implementing a safety assessment in a clinic seeing geriatric patients, in order to recommend/initiate appropriate referrals and services designed to keep older people safely in their homes		X	See, https://www.partners.org/Assets/Documents/Medical-Research/Clinical-Research/Clinical-QI-Checklist.doc
Reviewing pharmacy records to determine whether certain medications can be switched from IV to oral formulations in order to minimize risks and reduce costs		X	See, https://www.partners.org/Assets/Documents/Medical-Research/Clinical-Research/Clinical-QI-Checklist.doc
Implementation of a music therapy program in the in-patient pediatric units. A survey will be distributed to parents at the time of discharge to obtain feedback about the program.		X	Implementation of an evidence-based practice and evaluation to assess whether the program is having the desired impact is consistent with quality improvement that does not require IRB review.
Implementation of robotic pet therapy in a dementia unit with pre-post evaluation of data regarding delirium, falls, and the use of 1:1 companions to assess the impact of the program.		X	Implementation of an evidence-based practice and evaluation to assess whether the program is having the desired impact is consistent with quality improvement that does not require IRB review.
Implementation of a modified version of an evidence-based toolkit intended to support breastfeeding-friendly practices in clinical settings with pre and post assessment of patient data to determine effectiveness.	X		When an evidence-based tool is modified and the effectiveness of the modified practice is evaluated, the activity is likely research that requires IRB review.

CASE	HSR or QI that requires review	QI	NOTES
Implementation of a newly developed educational intervention intended to reduce fall rates. Three units will receive the education, three units will not. Fall rate data will be compared between the units as well as to historical data for each unit. The results will be shared with stakeholders and presented at a conference.	X		The educational intervention is novel, not all units will receive it, and the purpose is to test effectiveness of the intervention. The data will be used locally but will also be disseminated.
Implementation of behavioral therapy using a method that has been adapted to accommodate the needs of addicted individuals with cognitive dysfunction. One group will receive the adapted method while the other group will receive the current standard. Surveys and assessments will occur at set intervals.	X		The standard of care approach to behavioral therapy has been adapted and the effectiveness of the modified approach is evaluated, the activity is likely research that requires RB review.

¹ References:

1. Baily, M., et al. (2006). The Ethics of Using QI Methods to Improve Health Care Quality and Safety. *Hasting Center Special Report*. Retrieved from <https://www.thehastingscenter.org/publications-resources/special-reports-2/the-ethics-of-using-qi-methods-to-improve-health-care-quality-safety/>
2. Appendices adapted from the Children’s Hospital of Philadelphia website. Retrieved from <https://irb.research.chop.edu/quality-improvement-vs-research>.
3. Appendices adapted from the following publication: Ogrinc, G., et al., (2016). An Instrument to Differentiate between Clinical Research and Quality Improvement. *IRB Ethics & Human Research*. Retrieved from https://www.thehastingscenter.org/irb_article/an-instrument-to-differentiate-between-clinical-research-and-quality-improvement/.
4. Appendices adapted from the Partners Quality Improvement Checklist. Retrieved from <https://www.partners.org/Assets/Documents/Medical-Research/Clinical-Research/Clinical-QI-Checklist.doc>.
5. OHRP Quality Improvement Activities Frequently Asked Questions. Retrieved from <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/fag/quality-improvement-activities/index.html>.