Hebrew SeniorLife staff and faculty engage in activities to improve the quality of clinical care and service programs for the seniors and their family members who are served each day. Some quality improvement (QI) activities are designed to simply collect information and feedback about HSL programs and initiatives for internal purposes. Increasingly however, staff and faculty are conducting research in order to obtain data about program and initiative effectiveness and outcomes. This guidance document is intended to serve as a tool to assist HSL staff and faculty in determining when activities are considered quality improvement, and when those quality improvement activities cross the threshold into research involving 'human subjects', requiring IRB review and oversight.

In general, if activities are *limited to* implementing a practice solely for the purpose of improving patient care or delivering healthcare, or measuring and reporting provider data for clinical, practical or administrative purposes, those activities do not meet the definition of 'research'. However, if QI projects involve systematic investigations designed or intended to develop generalizable knowledge (e.g. to evaluate the effectiveness of the proposed program in order to guide policy or clinical practice changes), then the QI project would be considered research.

QI projects may constitute research because the program being implemented qualifies as a research intervention performed to evaluate an untested QI program's effectiveness (i.e., the program is implemented for a research purpose or is altered or controlled in some way to answer a research question); alternatively, QI projects may contain a research aspect separate and apart from the implementation of the QI program itself if HSL faculty and staff wish to study the implementation of the program (to understand various factors related to how such programs are implemented) *beyond* the collection of patient or provider data regarding the implementation for clinical, practical or administrative purposes. In the latter case, if the study of the QI program involves "human subjects" it (the study of the QI program) will require IRB review and oversight, even if the implementation of the program itself does not require IRB review and oversight.

Determination Process: Is IRB Review Required?

1. **The first step** in determining whether a quality improvement project is 'research' is to review the definition of research by the Department of Health and Human Services (DHHS):

   Research: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

2. **If the project is research, the next step** is to determine whether it involves 'human subjects', as defined by DHHS.

   Human Subject: A living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through Intervention or Interaction with the individual, or (2) information that is both Private Information and Identifiable Information. For the purpose of this definition:

Intervention means physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction means communication or interpersonal contact between investigator and subject.

Private Information means information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).

Identifiable Information means information that is individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information).

3. **If the project is both research and it involves human subjects, the project must undergo IRB Review.** You may use the HSL Quality Improvement Checklist (attached) to help determine whether your proposed activity is Quality Improvement/Measurement that does not require IRB review, or Quality Improvement Research that does require IRB review. If your project requires IRB review, please contact the IRB office (IRB@hsl.harvard.edu) for further instructions and access to the eIRB submission system.

4. **Publication of Results** may occur when an author believes others would be interested in learning about a program or initiative. The intent to publish the results of a quality improvement project does not determine whether the project requires IRB review. Publications about quality improvement programs that are *not* research should include a clear statement that the publication is the result of a quality improvement activity and should not refer to the activity as 'research'.

5. **If your quality improvement project is funded by a research grant** you should submit it for IRB review. Ordinarily, funding agencies award research grants to projects that the agency considers involving research activities. If a project is funded by some other entity (e.g., foundation, individual donor, etc.), the recipient of the award should submit the grant, contract, and/or funding application with a copy of a completed checklist (below) to the IRB office for assistance in determining whether the project will require IRB review.

QI vs. Research, version date 3.15.17

References:

OHRP Quality Improvement Activities – FAQs: http://answers.hhs.gov/ohrp/categories/1569

OHRP Correspondence to Peter J. Pronovost, M.D., Ph.D., The Johns Hopkins University School of Medicine (July 30, 2008); http://www.hhs.gov/ohrp/policy/Correspondence/pronovost20080730letter.html

Morris PE, and Dracup K, 2007, Quality Improvement or Research? The Ethics of Hospital Project Oversight,American Journal of Critical Care, v. 16 n.5, p. 424-426; http://ajcc.aacnjournals.org/content/16/5/424.full

Beyea SC, Slatterly MJ, 2008, Evidence-based Expert: Quality Improvement vs. Research: Are they the same? Staff Development Weekly: Insigned on Evidence-Based Practice in Education, November 21, 2008; http://www/hcpro.com/NRS-223824-975/Evidencebased-expert-Quality-improrvement-vs-research-Are-they-the-same.html

Lynn J, Baily MA, Bottrell M, Jennings B, Levine RJ, Davidoff F, Casarett D, Corrigan J, Fox E, Wynia MK, Agich GJ, O'Kane M, Speroff T, Schyve P, Batalden P, Tunis S, Berlinger N, Cronenwett L, Fitzmaurice JM, Dubler NN, James B, 2007, The Ethics of Using Quality Improvement Methods in Health Care, Annals of Internal Medicine, 1 May 2007;146(9):666-673, http://annals.org/article.aspx?articleid=734470

Yale University HRPP Policies and Procedures: 100GD5 HIC Clinical Quality Improvement Policy, and 100 CH9 Clinical Quality Improvement Checklist

Partners HealthCare Human Research Office Policies and Procedures: Quality Measurement Initiatives Policy and Clinical QI Checklist

QUALITY IMPROVEMENT CHECKLIST

Date:	**Department:**

Project Title:

Project Leader Name:

Instructions: Answer **YES** or **NO** to each of the following statements:	**YES**	**NO**
The purpose of the project is to: (mark which is true): • improve the process or delivery of care with established /accepted quality standards • implement change according to mandates of HSL's quality improvement programs • improve performance on a specific service or program	☐☐☐	☐☐☐
The project is **NOT** designed to: • develop or contribute to generalizable knowledge • test the effectiveness of a new intervention on clinical quality	☐☐	☐☐
The project does **NOT** follow a research design (such as testing a hypothesis, randomization of patients, or group comparison).	☐	☐
The project is flexible to make on-going changes as needed to improve the process or delivery of care, activity or program, and is guided by data, actual experiences or clinical results.	☐	☐
The project does **NOT** follow a protocol that over-rides individualized clinical decision-making.	☐	☐
There is **NO** intention of using the data for research purposes.	☐	☐
The project is conducted by clinicians and staff who provide care or are responsible for performance quality at HSL.	☐	☐
The project involves as 'participants' the clinicians or staff at HSL, patients who are seen at HSL, or residents who live in HSL facilities.	☐	☐
The project has **NO** funding from research-focused government agencies, sponsors or organizations, and is not receiving funding for the implementation research.	☐	☐
The project has **NOT** been approved by another institution's or agency's IRB as a research study and is not otherwise being conducted under IRB oversight.	☐	☐
The clinical practice unit (Department of Medicine, Adult Day Health, Nursing Services, MACU, etc.) agrees that this is a QI project that will be implemented to improve the process or delivery of care, activity or program. Department Head signature is required on this form.	☐	☐

ANSWER KEY:

• If the answer to **ALL** of the questions is **YES**, the activity is likely a Quality Improvement/Measurement activity that does not meet the definition of research, and therefore may not require IRB review.

• If the answer to **ANY** of the questions is **NO**, the project likely *does* meet the definition of research and will likely require IRB review.

If you are unsure of any information contained on this form, contact the IRB office: 617.971.5365, IRB@hsl.harvard.edu.

Project Leader Signature:	Date:
Department Head Signature:	Date: