**Cambridge Health Alliance**

**Researcher Guidance on Quality Improvement versus Research**

**Purpose/Introduction**

Investigators frequently experience confusion and/or frustration when trying to determine if a project constitutes [research](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.102) or [quality improvement](http://answers.hhs.gov/ohrp/categories/1569) (QI). Per Federal regulations, a [research](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.102) project involving [human subjects](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.102) requires IRB review and approval before it may begin. QI is not subject to Federal regulation or IRB review or oversight.

Before initiating an activity it is important to accurately determine if it is research or QI because Federal regulation does not give an IRB the authority to provide retrospective or retroactive approval. If a research project begins before IRB approval is obtained, it potentially jeopardizes not only the safety, welfare, and/or rights of participants, it also puts at risk the investigator's and/or the Institution's ability to conduct research and receive Federal funding.

Cambridge Health Alliance (CHA) has developed this guidance to help its researchers interpret these complicated issues and guide them on how to proceed when faced with these issues.

**Definitions**

Contribute to generalizable knowledge: Means that the purpose or intent of the project is to test or to develop scientific theories or hypotheses, or to draw conclusions that are intended to be applicable and/or shared beyond the populations or situations being studied. This may include:

* Presentation of the data at meetings, conferences, seminars, poster presentations, etc.;
* The knowledge contributes to an already established body of knowledge;
* Other researchers, scholars, and practitioners may benefit from this knowledge;
* Publications including journals, papers, dissertations, and master’s theses.

Source: CHA.

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. Identifiable private information.

*Intervention* includes both 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* includes communication or interpersonal contact between investigator and subject.

*Private information* includes 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).

Private information must be *individually identifiable* (*i.e.*, the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.” Source: The Office for Human research Protections (OHRP); 45 CFR 46.102(f). [Emphasis added.]

According to the OHRP [Guidance on Research Involving Coded Private Information or Biological Specimens](http://www.hhs.gov/ohrp/policy/cdebiol.pdf), OHRP generally considers private information or specimens to be individually identifiable as defined at [45 CFR 46.102(f)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.102) when such information can be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems.   
  
Conversely, OHRP considers private information or specimens not to be individually identifiable when they cannot be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems.

Quality improvement: "A systematic pattern of actions that is constantly optimizing productivity, communication, and value within an organization in order to achieve the aim of measuring the attributes, properties, and characteristics of a product/service in the context of the expectations and needs of customers and users of that product" Source: The Institute of Medicine.

QI involves all those planned and systematic actions necessary to provide adequate confidence that a product or service will satisfy given requirements for quality.

Research: “A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” Source: OHRP; 45 CFR 46.102(d)).

Systematic investigation: An activity that follows a predetermined plan for examining a particular issue, testing a hypothesis or research question, or developing a new theory that may include:

* Collection of quantitative or qualitative data;
* Collection of data using surveys, testing or evaluation procedures, interviews, or focus groups;
* Collection of data using experimental designs such as clinical trials; or
* Observation of individual or group behavior.

Source: CHA.

**Process/Procedures**

OHRP provides guidance on a methodical process to help determine if an activity is research or QI. It is important to note that the intent to publish is an insufficient criterion for determining whether a QI activity involves research.

Most QI efforts are not research subject to OHRP regulations; however, in some cases QI activities are designed to accomplish a research purpose, as well as the purpose of improving the quality of care. In such cases Federal human subject protection regulations ([45 CFR 46](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html)) may apply and the IRB should be contacted and consulted prior to initiating the project.

To determine whether Federal regulations apply to a particular QI activity, per OHRP, the following questions should be addressed in order:

1. Does the activity involve [research](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.102) (45 CFR 46.102(d));
2. Does the research activity involve [human subjects](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.102) (45 CFR 46.102(f));
3. Does the human subjects research qualify for an [exemption](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.101) (45 CFR 46.101(b)); **and**
4. Is the non-exempt human subject research conducted or supported by the Department of Health and Human Services or otherwise covered by an applicable Federalwide Assurance approved by OHRP?

If the answer to **all** of the 4 questions above is “no,” then the activity is not research and does not require IRB review or approval.

However, if the answer to one or more of the 4 questions above is “yes,” then the project does require submission to the IRB and IRB review and approval before the study may begin.

It may be difficult for a project leader to determine whether a project is research or QI. Also, circumstances differ between projects; even seemingly small differences between projects may have a large impact on the determination. If any uncertainty exists the project leader is to contact the IRB office for additional guidance and assistance before proceeding with the activity.

**Additional Interpretation**

Of particular application to CHA personnel is OHRP opinion about whether QI activities are subject to Federal human subject protection regulations (45 CFR part 46) if their purposes are limited to: (a) delivering healthcare, and (b) measuring and reporting provider performance data for clinical, practical, or administrative uses.

Per OHRP, such QI activities do not satisfy the definition of “research” ([45 CFR 46.102(d)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.102); see above). As a result, Federal human research regulations (45 CFR 46) do not apply to such QI activities; under these regulations a requirement does not exist for such activities to undergo IRB review, or for these activities to be conducted with provider or patient informed consent.

The clinical, practical, or administrative uses for such performance measurements and reporting could include, for example, helping the public make more informed choices regarding health care providers by communicating data regarding physician-specific surgical recovery data or infection rates. Other practical or administrative uses of such data might be to enable insurance companies or health maintenance organizations to designate higher performing sites preferred providers, or to allow other third parties to create incentives rewarding better performance.

In addition, there are types of QI efforts that are considered to be research that are subject to Federal regulations (45 CFR 46). For example, per OHRP, if a project involves introducing an untested clinical intervention for purposes which include not only improving the quality of care but also collecting information about patient outcomes for the purpose of establishing scientific evidence to determine how well the intervention achieves its intended results, that QI project may also constitute human subject research under 45 CFR 46 regulations; the IRB should be contacted and consulted prior to initiating the project.

**Summary of Research and QI Characteristics**

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| **Research** | **QI** |
| Research projects must meet IRB requirements for protection of human subjects. Investigators conducting research must also meet Health Insurance Portability and Accountability Act (HIPAA) requirements regarding authorization to use or disclose protected health information (PHI). | QI projects are not subject to IRB requirements. Members of the CHA workforce (including Medical Staff) are allowed by HIPAA to use PHI for QI projects without patient authorization. |
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| The following are characteristics of Research:   * PI will have a specific hypothesis or research question. * PI will conduct an organized review of relevant literature. * PI will develop a research design that will lead to scientifically valid findings. Elements of a research design include: Control groups; random selection of subjects, statistical tests, sample design, *etc.* * Goal is to advance general knowledge in the academic/scientific community or in the PI’s profession. | The following are characteristics of QI:   * PI will identify a clinical program or protocol that s/he wants to improve. * PI may review other clinical programs or protocols at other institutions, but does not plan a full literature review. * PI will design a project using QI methods (such as Plan-Do-Check-Act or PDCA cycle) aimed at producing change within our organization. Design does not include sufficient research design elements to support a scientifically valid finding. |

**Examples of studies that typically require IRB Review:**

* Pilot studies that involve human subjects.
* Use of identifiable information from medical records, student records, employment records, or other private sources.
* Activities where data about human subjects are collected through interaction or intervention with subjects, such as surveys (paper, online, telephone, etc.), interviews, focus groups, cognitive testing, etc.
* Investigations that include humans to examine devices, products, food, drugs, supplements, etc.

**Examples of activities that generally do NOT require IRB Review:**

* Data collected for internal departmental or administrative purposes, such as teaching evaluations, student performance data, etc.
* Activities designed solely for QI or evaluation of a particular program, course, etc.
* Oral histories or biographies (unless data will also be used to contribute to generalizable knowledge).
* Training activities, unless the training activity is conducted for research purposes.
* Examples of implementing a practice and collecting patient or provider data for non-research clinical or administrative purposes:
* A radiology clinic uses a database to help monitor and forecast radiation dosimetry. This practice has been demonstrated to reduce over-exposure incidents in patients having multiple procedures. Patient data are collected from medical records and entered into the database. The database is later analyzed to determine if over-exposures have decreased as expected.
* A group of affiliated hospitals implements a procedure known to reduce pharmacy prescription error rates, and collects prescription information from medical records to assess adherence to the procedure and determine whether medication error rates have decreased as expected.
* A clinic increasingly utilized by geriatric patients implements a widely accepted capacity assessment as part of routine standard care to identify patients requiring special services and staff expertise. The clinic expects to audit patient medical records to evaluate if the assessments are performed with appropriate patients, and will implement additional in-service training of clinic staff regarding the use of the capacity assessment in geriatric patients if it finds that the assessments are not being administered routinely.

**Resources/References**

* Cambridge Health Alliance policy “Definition of Research versus Quality Improvement (A-COM-0006) <http://www.challiance.org/Resource.ashx?sn=ACOM0006ResearchvsQualityImprovement>
* Department of Health and Human Services 45 Code of Federal Regulations (CFR) 46: <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.102>
* National Institutes of Health, Frequently Asked Questions From Applicants, Human Subjects Research – Definitions (version dated February 11, 2010): <http://grants.nih.gov/grants/policy/hs/faqs_aps_definitions.htm#276>
* Office for Human research Protections Quality Improvement Activities - FAQs: <http://answers.hhs.gov/ohrp/categories/1569>