CAMBRIDGE HEALTH ALLIANCE Title: Definition of Research versus Quality Improvement	Replaces (supercedes) Title:	Policy Number: **A-COM-0006** Policy Type: **Administrative** Effective Date: 07/01/03
Area of Operation(s): Institutional Review Board (IRB)	Policy Chronicle: Date Original Version of Policy was Effective: 07/01/03 Date of Previous Review/Revision to the Policy: 07/01/03 Date of Most Recent Review/Revision to the Policy: 07/01/06 Signature of Most Recent Reviewer/Reviser: _____ Printed Name of Most Recent Reviewer/Reviser: Glover Taylor	
Regulatory Agency/Standards: Department of Health and Human Services Office of Human Research Protections Office of Civil Rights National Institutes of Health	Approvals: Chair, Institutional Review Board:_____ Stephen Pinals, MD Chief Executive Officer:_____ Dennis Keefe	
Keyword(s):	Research, Quality Improvement, IRB, QI	

I. Purpose: This policy establishes the definition of Research versus Quality Improvement (QI). The policy applies to all projects conducted at the Cambridge Health Alliance or by Cambridge Health Alliance employees. Whenever there is uncertainty as to whether a project is considered research or QI the project leader should request guidance from the Institutional Review Board (IRB).

II. Personnel: All Alliance Staff

III. Policy: It is the responsibility of the project leader who initiates a project to determine if it is research or QI. Research projects must comply with specific policies and regulations designed to protect human subjects and privacy rights. Quality Improvement projects are not required to act in accordance with research policies and regulations. However, it may be difficult for a project leader to determine if their project is research or QI. Since this determination may have a significant impact on the project design, procedures, and regulatory compliance, the project leader should not hesitate to ask the IRB for guidance. There are serious consequences for not following Cambridge Health Alliance policies and Federal regulations when conducting research.

IV. Procedure:

How to use this guide: The first section provides definitions for Research and Quality Improvement. The second section provides certain characteristics typically associated with research and QI projects. Once you review the definitions and characteristics, you should be able to determine the appropriate category for your project. If you determine that the project is similar to both definitions, then the project is research.

Section 1: Definitions

What is Research? The Common Rule defines research as “a systematic investigation including research development, testing and evaluation designed to develop or contribute to generalizable knowledge”. [Source: Code of Federal Regulations 45CFR46.102]

What is Quality Improvement (QI)? Quality Improvement is defined as "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]

Please note: The IRB cannot retroactively approve research.

Section 2: Characteristics of Research Projects and Quality Improvement Projects

Research	**Quality Improvement**
Research projects must meet IRB requirements for protection of human subjects. Researchers conducting research must also meet HIPAA requirements regarding authorization to use or disclose protected health information.	Quality Improvement projects are not covered by IRB requirements. Members of the CHA workforce (including Medical Staff) are allowed by HIPAA to use protected health information for Quality Improvement projects without patient authorization.
Characteristics of Research: • One of the main goals of the project is to advance general knowledge in the academic, scientific, or professional community. • The project will have a specific hypothesis or research question. • The project involves an organized review of relevant literature. • The project will be conducted using 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. • Most of the patient/subjects are not expected to derive a personal benefit from the knowledge gained. • One goal of the project is to generate, evaluate or confirm an explanatory theory or conclusion and invite critical appraisal of that conclusion by peers through presentation and debate in public forums.	**Characteristics of Quality Improvement:** • The project identifies specific services, protocols, clinical practices, or clinical processes or outcomes within a department, clinical program or facility for improvement. • The project team may review available literature and comparative data, or clinical programs, practices or protocols at other institutions in order to design improvement plan, but do not plan a full scientific literature review. • The project design uses established quality improvement methods (such as PDSA cycle) aimed at producing change within Cambridge Health Alliance. • The project design does not include sufficient research design elements to support a scientifically valid finding. • Most of the patients who participate in the project are expected to benefit from the knowledge gained. • The project does not impose any risk or burden on the patients. • The main goal of the project is to improve patient care, a clinical program or service at Cambridge Health Alliance.