Guidance related to Quality Improvement Projects
IRB Guidance Document

Overview

The majority of quality improvement projects do not require review by the IRB. There are, however, cases where the project would fall under the purview of the IRB. Projects that qualify as "research" and which involve "human subjects," as defined in the federal regulations and further explained below, would require IRB review under Texas A&M University policy. The most common reason for QI projects to require IRB review is that they are projects involving systematic investigations designed to develop generalizable knowledge. Terms such as 'research' and 'human subject' have distinct definitions in the federal regulations, and use of such terms may invoke a set of requirements that perhaps do not apply. When referring to QI projects, it is best to avoid use of the terms 'research' 'study' and even 'study intervention.' More appropriate terms might include 'project' or 'proposal.'

Quality Improvement Defined

Quality Improvement (QI) involves systematic, data-guided initiatives or processes designed to enhance service delivery in a particular setting. QI is intended to use experience to identify effective methods, implement the methods broadly, and evaluate the impact or effect of the implemented changes. As such, QI is an intrinsic part of good program practice where lessons learned are used to enhance future service delivery for individuals at the institution in which the QI activity is implemented. A QI project may involve implementing a practice to improve service delivery, the quality of patient care, and/or collecting 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. Note that these "best practices" represent accepted, standard activities, or evidence-based approaches to caring for patients (such as hand-washing, ordering mammograms for eligible women, or improving glucose control in diabetic patients), rather than experimental/unproven interventions or activities (see "Research" below). Results of a QI project could and perhaps should be shared with others, either via presentation or publication. QI activities that meet this description would not be considered human subjects research.

Definition of Research and Human Subject

Federal regulations define research as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge" (45CFR46). Under this definition, the project must be designed to generate conclusions that can be applied in or be predictive of similar circumstances. Thus, a case study of a single individual would not be considered research. A human subject is defined in the Federal regulations as 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) obtains identifiable private information" (45CFR46.102(f)). Key to this definition is that the information collected is about an

identified person and is intended for research. It should be noted that a QI project certainly may involve 'individual participants,' but may not involve 'human subjects.'

QI Projects Requiring IRB Review

If a proposed project will involve collecting information about or from an individual AND will be used to inform broad policy or generalize findings, then the project must be submitted to the IRB for review. Note that the determination of whether or not a project constitutes research is separate from whether or not the project involves human subjects and only when both definitions are met does the project require IRB review.

For example, the following may be indicators that IRB review is required:

- The study is funded by an agency or sponsor which seeks to support projects designed to create generalizable knowledge such as U.S. Department of Health and Human Services, National Institutes of Health, National Science Foundation, Agency for Healthcare Research and Quality (AHRQ), pharmaceutical sponsor, etc.
- The study involves multiple individuals' perspectives on the issue of interest AND these perspectives are analyzed to reach generalized conclusions.

The following examples are projects that would not require IRB review:

- Data collection for internal departmental, school/agency, or other administrative purposes, including teaching evaluations, customer service surveys, etc.
- Strategic plan implementation activities that are non-research, including internal evaluations, customer satisfaction assessments, knowledge gain from standard program implementation, program efficiency assessments, and economic impact briefs.
- The project compares and contrasts policies, procedures, or events to identify general commonalities or inform policy decisions without the collection of information about individuals (e.g. literature review).
- The project involves students using research methods (e.g. interview and/or survey techniques), where the results of those methods will be used to evaluate the student's ability to apply these techniques, and the results will not be used to test a hypothesis.