**Procedure for Registering Quality Improvement Projects**

**BACKGROUND**

Quality Improvement (QI) activities have been defined as systematic, data-guided initiatives designed to enhance health care delivery in a particular setting. QI is an integral part of good clinical practice whereby results are used to inform the provision of healthcare services for patients at the local institution. Patient populations are frequently the targets of QI project and the distinction between QI activities and regulated human research is not always clear. There can be understandable confusion about whether QI activities fall under the jurisdiction of the IRB. Prior IRB approval is required when any project, in whole or in part, meets the federal definition of human research. Attributes such as publication of findings, methodology, or the systematic collection of data, do not necessarily differentiate regulated human research from QI activities because these attributes can be shared by both research and non-research activities. Additionally, activities that start out as QI projects may lead to regulated human research when a decision is made to use previously collected QI data for a research purpose.

The range of traditional QI activities is broad, but they typically are projects:

* Aimed at improving local systems of care, or improving the performance of institutional practice;
* Designed to bring about immediate improvements in health care delivery;
* Designed to verify that promising methods of care introduced into clinical practice result in improved outcomes
* Intended to compare a program/process/system to an established set of standards such as standard of care, recommended practice guidelines, or other benchmarks.

According to federal guidance, “the intent to publish is an insufficient criterion for determining whether a quality improvement activity involves research.” This guidance document addresses UTHealth’s approach to reviewing QI projects that do not meet the regulatory definition of human subjects research.

**PURPOSE AND SCOPE**

The purpose of this document is to outline the process for reviewing quality improvement projects involving patients or patient care processes to determine if the project meets the definition of human subjects research as defined by the human subjects regulations (45 CFR 46.112). This policy applies to all quality improvement projects that are conducted by UTHealth faculty and staff.

**KEY TERMS**

***Continuous Quality Improvement (CQI)*** refers to an ongoing effort to increase an agency’s approach to manage performance, motivate improvement, and capture lessons learned in areas that may or may not be measured as part of accreditation. It is an ongoing effort to improve the efficiency, effectiveness, quality, or performance of services, processes, capacities, and outcomes.

***Quality Assurance (QA)*** refers to a broad spectrum of evaluation activities aimed at ensuring compliance with minimum quality standards. The primary aim of quality assurance is to demonstrate that a service or product fulfills or meets a set of requirements or criteria.  QA is identified as focusing on “outcomes,” and CQI identified as focusing on “processes” as well as “outcomes.”

***Quality Improvement (QI)*** refers to activities aimed at improving performance and is an approach to the continuous improvement of the processes of providing services to meet the needs of the individual and others.

***Research*** is defined as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

**PROCEDURE**

Many but not all departments in the UTHealth schools have a process for submission, review and approval of quality improvement projects. The procedure outlined in this document is meant to complement the department review process.

UTHealth faculty and staff planning a quality improvement project involving UTHealth patients or UTHealth patient care processes, must register their project before initiation using [the QI Project Registration Form](https://redcap.uth.tmc.edu/surveys/?s=T7DX9L4KTE). The registration includes basic information about the project, uploading the project plan and answering a few questions regarding the project. The name and email address of the division or department Quality Improvement official should be provided during registration.

When a new project is registered, IRB staff will review the details and determine if the registration is complete. If the form is not complete or additional information is needed, the IRB will work with the project lead to obtain the information.

If IRB determines that the project is a quality improvement activity and does not meet the definition of human subjects research, IRB staff will send a letter to the project lead stating that the registration was accepted. A copy of the letter and the completed registration form will be sent to the division/department Vice Chairs for Quality Improvement.

If IRB staff determines that the project needs to be reviewed by CPHS or is unsure whether it needs to be reviewed by CPHS, the IRB staff has the option to seek additional review by the VP, Human Research Protection Program, Chair or Vice Chair of any of the four CPHS panels, division/department QI official or others. If the decision is that the project meets the definition of regulated human subjects research, the IRB staff will send a letter with the determination and instructions to submit the project to CPHS via iRIS.

The QI Project Registration form collects information on estimated project end date. A month after this end date, a notice will be sent to the Project Leader to complete a follow up survey form about the status of the project.

IRB staff will send periodic reports to each division/department QI lead about the activities registered by that division/department.

**REFERENCES**

1. OHRP Quality Improvement Activities FAQ - [http://www.hhs.gov/ohrp/regulations-and policy/guidance/faq/quality-improvement-activities/](http://www.hhs.gov/ohrp/regulations-and%20policy/guidance/faq/quality-improvement-activities/)
2. CPHS policy - Research Which Requires Review by IRB

**ATTACHMENTS**

1. QI Project Charter Template (it is not mandatory to use this template)
2. UTHealth Departmental Quality Improvement Resources