



TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER

Operating Policy and Procedure

HSC OP: 73.18 Quality Improvement Project Review

PURPOSE: The purpose of this HSC OP is to detail the process available for formal review and approval of quality improvement (QI) activities conducted by TTUHSC faculty including the function of a Quality Improvement Review Board (QIRB). The criteria for projects to be considered QI are specified herein as are the composition and functions of the QIRB.

REVIEW: This HSC OP will be reviewed by June 1 of each even-numbered year (ENY) by the Associate Vice President for Research Integrity, with recommendations for revision forwarded to the Senior Vice President for Research (SVPR).

POLICY/PROCEDURE:

1. Introduction

Quality improvement (QI) projects involve the systematic collection and analysis of data and implementation of interventions designed to improve the quality of clinical care and/or educational programs for a distinct population in a specific setting. Quality improvement projects will typically involve collection and analysis of patient, student or employee data. Participating in and conducting QI projects is considered a key competency and an expectation of the practicing healthcare professional. Thus, as a public institution for health sciences education and clinical services, TTUHSC has a responsibility to promote and support the safe and effective conduct of QI initiatives while also protecting the persons (patients, students, or employees) whose behavior is being monitored and/or who are participants in QI interventions. Improper review and conduct of QI projects may put TTUHSC at risk for non-compliance with federal regulations, state laws and local policies, including HIPAA regulations. A formal review process for QI projects will ensure a) data collection and involvement of humans associated with the QI project indeed meet QI standards; and b) the project does not require Institutional Review Board (IRB) review and oversight.

It is sometimes the intent of the QI project team to disseminate the results of their work, in which case documentation of formal review and approval is generally required by peer-reviewed journals and professional organizations. The quality improvement project review process and the functions of the Quality Improvement Review Board (QIRB) which are delineated herein will serve as that formal review and approval. The QIRB also formally reviews other non-research projects such as program implementation and evaluation, and evidence-based practice projects for the purposes of dissemination.

2. Applicability

This policy applies to all TTUHSC faculty, staff, residents and students (including post-doctoral students) involved in the design or conduct of quality improvement projects that meet the criteria defined within this policy (Sections 4 and 5).

3. Definitions

Principal Investigator / Project Leader: The faculty member, as defined in HSC OP 73.08, who has responsibility for design and oversight of the quality improvement project. All quality improvement projects reviewed by the QIRB require a project leader.

Quality Improvement: Systematic data guided activities designed to bring about immediate improvements in a particular setting for a distinct population¹.

Process Improvement: Assessing a defined series of linked steps in place to transfer inputs into outputs² to identify opportunities for change that will result in increased efficiency or effectiveness. (For example, a process of medication administration for a hospitalized

patient involves a series of linked steps that begin at the time an order is received for the medication until the medication is actually administered to the patient; assessing the steps in this process can be beneficial to identify opportunities to reduce errors and improve efficiency for medication administration)

Evidence-Based Practice (EBP) Project: Implementation of a change in practice based on the best available evidence; typically follows an EBP model for implementation such as the IOWA model.

4. Applicable Projects and Criteria:

Improvement projects to be reviewed by the QIRB are Process Improvement, EBP, and QI projects that meet the following criteria:

- a) Meets the formal definition of Process Improvement, EBP, or QI as described above.
- b) Intent: Addresses a gap in performance in a clinical or educational setting and applies a proven/evidence-based approach to address the gap. The intent is NOT to discover new, generalizable knowledge.
- c) Design: Uses QI methods such as the PDSA (Plan – Do – Study – Act) model, process improvement, or an evidence-based practice (EBP) model, and statistical methods to evaluate improvements or change over time
- d) Setting: Single setting and specific location. System-wide improvements are acceptable where the deployment of the project occurs at multiple sites and different locations but under the authority of one system.
- e) Benefit: results of project will provide direct benefit to participant group being studied (i.e., students, patients)
- f) Data: Involves data collection and analysis that is specific to the project and is not part of routine, ongoing data collection activities for the operational unit
- g) HIPAA and Protected Health Information: HIPAA waiver is not typically required if the project leader and team have routine access as part of their responsibilities within the institution associated with treatment, billing, performance monitoring, and/or compliance; data are de-identified for analysis and reporting purposes.
- h) Dissemination: Intent to publish or otherwise disseminate the results of the project beyond the operational unit.

5. Exceptions to the process:

- a) The review process will not apply to routine data collection activities that are part of required, ongoing program evaluation such as patient satisfaction surveys and course assessment surveys; actions taken as a result of routine data collection such as minor changes in clinical operations to address patient satisfaction and minor changes in teaching approaches or course activities to address course assessment data.
- b) QIRB review will generally not be offered for projects that meet ALL of the following criteria:
 - i. No additional risk or harm is imposed on participants (patients, students, employees) compared to everyday operations
 - ii. Design is simple with no data collection and analysis beyond routine data collected as part of routine operations
 - iii. There is no intent to publish or otherwise disseminate results of the project

6. Student Projects:

- a) If a TTUHSC student is conducting an improvement project entirely at another institution, and has obtained approval for the project from the QIRB (or equivalent) of the other institution, then the TTUHSC QIRB approval is not required. However, the student should submit a copy of project approval documentation to the TTUHSC QIRB as well as provide the name of a TTUHSC faculty member responsible for the project.
- b) If a TTUHSC student improvement project is conducted at another institution that does not have a comparable oversight process in place, then the project should be reviewed by the TTUHSC QIRB under the name of a TTUHSC faculty member who is responsible for the project.

7. **Quality Improvement Project Review Process:**

- a) A project leader planning to conduct a QI or EBP project which meets the criteria for the QIRB Review process should complete the *Quality Improvement Review Board Application* (Attachment A) and submit for approval to the QIRB Director (QIRB@ttuhsc.edu) for review.
 - i. If the project is conducted at a non-TTUHSC site, the project leader shall also submit a letter of support from the project site.
- b) Every effort will be made to conduct an initial assessment of the project with communication back to the project leader on the status of the project within 7-10 business days.
- c) QIRB submissions will be reviewed and acted upon based on the following procedure:
 - i. The QIRB Director will conduct the initial review. The Director will then forward the project to one board member for a secondary review.
 - ii. If the initial and secondary reviews indicate the project clearly meets the criteria as outlined in #4, the QIRB Director will send appropriate notification to the project team.
 - iii. If the project is determined by initial review to meet criteria for research involving human subjects, the project leader will be notified to submit the project to the TTUHSC IRB for review.
 - iv. If a determination about meeting project criteria (#4) is unclear from the initial review, the Director will contact the project team to obtain additional clarifying information, and then forward the project for secondary QIRB review or IRB review as appropriate.
 - v. The QIRB Director will manage and maintain copies of written communications to the Project Leader regarding QIRB decisions and/or request for more information.
 - vi. Documents created by the QIRB Director including finalized minutes of QIRB meetings, correspondence, and electronic letters have the full approval of the QIRB Chair/designee and have the authority of signed documents. Handwritten signatures of the QIRB Chair/designee are not required under this policy.

8. **Quality Improvement Review Board (QIRB):**

- a) *Purpose:* The purpose of the QIRB is to ensure the ethical oversight of improvement projects and determine their appropriateness, safety, feasibility and distinct design separate from research.
- b) The QIRB and any sub-committees established under this policy shall be considered “medical committees” as defined under Texas Health and Safety code 161.031 and/or other applicable state and federal statutes. All documents generated by, submitted to, or used for the purposes of fulfilling QIRB duties are confidential and privileged as “medical committee documents.”
- c) *Membership:* The QIRB will be composed of at least six (6) members. Efforts will be made to include at least one representative from each TTUHSC school (Graduate School of

Biomedical Sciences, Medicine, Nursing, Pharmacy, Population and Public Health, and Health Professions). Representatives from regional campuses can dually serve as both a campus and a school representative. At least one member will also represent the IRB. The Associate Vice President for Research Integrity will serve as an *ex-officio*, non-voting member of the Board.

- d) *Membership Term*: Members will be appointed by the Senior Vice President for Research to a two-year term and may be reappointed to serve additional years. The Chair of the QIRB will be appointed to a two-year term from the membership by the Senior Vice President for Research.
- e) *Meetings*: The QIRB will convene meetings at least quarterly and more often if needed depending on the quantity of application submissions requiring review by the full Board. The QIRB Director will be responsible for scheduling and coordinating all meetings. The QIRB may convene meetings and/or conduct project reviews and voting by email or conference call to facilitate efficiency.
- f) *Quorum*: The QIRB can approve, deny or request more information on a QI project with at least half of the appointed members voting. A majority of those voting must agree on the outcome.
- g) *Materials*: Prior to each convened meeting of the QIRB, members will be given materials sufficient for conducting the business of the meeting, including the *Quality Improvement Review Board Application* scheduled for review. Materials may be provided to members via secure email prior to the meeting.
- h) *Minutes*: Written minutes of each convened meeting will be in sufficient detail to document attendance and presence of a quorum; actions taken by the QIRB; and the vote on these actions including number of members voting for, against, or abstaining. Meeting minutes and materials shall be maintained for a minimum of 3 years after the meeting date. The QIRB Director will be present at each meeting and will be responsible for taking minutes and maintaining records.

¹ C. Lynn, J., M.A. Baily, M. Bottrell, et al. (2007). The ethics of using quality improvement methods in health care. The Hastings Center. Available online at <http://www.thehastingscenter.org/publications-resources/special-reports-2/the-ethics-of-using-qi-methods-to-improve-health-care-quality-safety/>.

² Langley, G. J., Moen, R. D., Nolan, K. M., Nolan, T. W., Norman, C. L., & Provost, L. P. (2009). *The improvement guide: A practical approach to enhancing organizational performance* (2nd Ed). San Francisco, CA: Josseybass.com