

QA/QI/EBP/HSR Project Assessment Tool

Researchers are encouraged to use this tool to help determine whether a project can be considered Quality Improvement, Quality Assurance, Evidence Based Practice, or Human Subject Research. This is **not** an IRB application for approval. **If you feel your project fits the definition for Human Subject Research, please contact the UTA IRB office for further assistance** – RegulatoryServices@uta.edu.

Quality Improvement (QI) and Quality Assurance (QA) projects:

Implementing local, setting-specific improvements to the quality or processes of patient care

- Focuses on using systematic initiatives designed to improve clinical care, clinical processes, patient safety, health care operations, clinical services, outcomes, and programs; however, may not require an extensive literature review.
- Study design has no generalizable external application; there is no intention to use the data collected to test a generalizable hypothesis or to create generalizable conclusions for the field as a whole.
- Intended to use the researcher's experiences to identify effective methods within a local clinical setting and evaluate the immediate impact or effect of the implemented changes on that specific setting only.
- May involve the collection of patient data; however, knowledge gained from the project will not be applied to develop new techniques, interventions, procedures, or processes outside of the initial project setting.
- Activities of the project are usually "best practices," "routine care," or "standard practice" and conducted by staff where the project will take place. May also attempt to correct workflow processes, improve efficiencies, reduce variations in care, and address clinical administrative or educational problems.
- Results of a QI/QA project could be shared with others, but when they are, the report explains how the project was implemented and the outcomes achieved in that specific setting.

Evidence-Based Practice (EBP) projects:

Implementing evidence-informed improvements to local processes and patient care

- Integrates the best available research evidence with clinical expertise and patient values to improve outcomes.
- Involves translating the available evidence and applying it to clinical decision-making and practices. Often involves a literature search to find the best available information to inform clinical practice.
- Focuses on using interventions that have already been tested or validated and shown to be effective in existing literature; does not intend to find new, untested interventions or to validate new or existing tools.
- May involve the collection of patient data; however, knowledge gained from the project will not be applied to develop new techniques, interventions, procedures, or processes outside of the initial project setting.
- Results of an EBP project could be shared with others, but when they are, the focus is on how the investigator chose the best available evidence and how that evidence was then applied in the clinical setting, as well as what the outcomes were in that setting after implementation.

Human Subject Research (HSR) projects:

*****IRB review is required prior to the initiation of all HSR Projects.*****

Discovering new ways to improve processes and patient care with the intention of sharing scientific findings

- Involve a systematic investigation, including research development, testing and evaluation (*i.e. pilot studies*), designed to develop or contribute to generalizable knowledge.
- Often involves a literature search; when gaps in the existing literature are found, or when an investigator sees an opportunity to change a tested intervention or to build on an existing topic, this generates a new research hypothesis, which is then tested in a new research study.
- Attempts to generate new knowledge or to validate existing knowledge based on a theory or hypothesis; may intend to test a new intervention without known effectiveness for the purpose of establishing scientific evidence to determine how well the intervention achieves its intended results, or may also intend to develop new conclusions about the characteristics of people in the research.
- Involve the collection of data about humans, either through interaction or intervention with the human participants, or via the analysis of existing individually identifiable, private data about living humans.
- The project will be conducted using a design that will lead to scientifically valid findings (e.g., control group, randomization, sample design, etc.).
- One of the main goals of the project is to advance general knowledge in the academic, scientific, or professional community or fill a gap in current literature; results are shared with the intention of contributing to generalizable knowledge.