TORRANCE MEMORIAL
A CEDARS-SINAI AFFILIATE

**RESEARCH VERSUS QUALITY IMPROVEMENT (QI) / PERFORMANCE IMPROVEMENT (PI) GUIDE AND CHECKLIST**

**PURPOSE**

There is often confusion in determining whether Quality Improvement (QI) or Performance Improvement (PI) activities are Research and require review by the Institutional Review Board (IRB). This guide is offered as a tool to help determine if the proposal is research or QI/PI.

**Whenever there is uncertainty as to whether a project is considered research or QI/PI the investigator should request a consult from the IRB Chair.**

**DEFINITIONS**

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

A **"systematic investigation"** is an activity that involves a prospective plan that incorporates data collection, either quantitative or qualitative, and data analysis to answer a question. Examples of systematic investigations include: surveys and questionnaires, interviews and focus groups, analyses of existing data or biological specimens, epidemiological studies, evaluations of social or educational programs, cognitive and perceptual experiments, or medical chart review studies.

Investigations designed **to develop or contribute to generalizable knowledge** are those designed to draw general conclusions, inform policy, or generalize findings beyond a single individual or an internal program (e.g., publications or presentations). However, research results do not have to be published or presented to qualify the experiment or data gathering as research. The intent to contribute to "generalizable (scholarly) knowledge" makes an experiment or data collection research, regardless of publication.

*Research that never is published is still research. Subjects in research studies deserve protection whether or not the research is published.*

A **human subject** is as a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual; or (2) identifiable private information.

**Intervention** includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

**Interaction** includes communication or interpersonal contact between investigator and subject.

**Private information** must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

*Notes:*

- *Thesis or dissertation projects involving human subjects conducted to meet the requirement of a graduate degree are usually considered generalizable, and require IRB review and approval.*
- *The mere intent to publish the findings of a project does not require IRB review as long as the publication does not refer to the activity as research, and makes it clear the publication is the result of a quality improvement.*

FDA regulations [21 CFR Part 50 and 56] define a **clinical investigation** as any experiment that involves a test article.

A **test article** is any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the Federal Food, Drug, and Cosmetic Act. FDA regulations define **human subject** as an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient.

Examples of clinical investigations include: investigational drug clinical trials, research testing the safety and effectiveness of an investigational device, or medical outcomes study comparing approved drugs/devices.

The state of California also requires IRB review of studies using state issued death records (certificates and indices). Refer to CA Health and Safety Code, Sections 102231-102232 for more information.

**Quality Improvement (QI) or Performance Improvement (PI) Projects:** Internal projects related directly to improving or assessing the performance of the institution, its employees or clinical outcomes within the mandate of the institution. Projects are considered to be quality improvement or performance improvement if they involve the systematic monitoring, assessment or evaluation of the various aspects of an organization to ensure that standards of quality are being met, or to correct or enhance the various aspects of the organization. These projects do not seek to establish generalizable knowledge.

## CHARACTERISTICS OF
## RESEARCH AND QUALITY IMPROVEMENT/PERFORMANCE IMPROVEMENT

| | Research | Quality Improvement/ Performance Improvement |
|---|---|---|
| **Purpose** | Designed to develop or contribute to generalizable knowledge.<br>To test a hypothesis or to establish clinical practice standards where none are already accepted. | Designed to implement knowledge, assess a process or program as judged by established or accepted standards.<br>To improve performance on a specific service, protocol, clinical practice, process, or outcome within a department, clinical program or facility. |
| **Starting Point** | Intended to answer a question or test a hypothesis. | Purpose is integral to ongoing management system for delivering health care. To improve performance. |
| **Design** | Follows a rigid protocol that remains unchanged throughout the research. | Adaptive, iterative design.<br>Uses established quality improvement methods (e.g. PDSA cycle, Six Sigma, or Lean methodologies) aimed at producing a change within the Torrance Memorial Health System. |
| **Data Collection** | Systematic data collection. | Compare a program/process/service to an established set of standards. |
| **Analysis** | Statistically prove or disprove hypothesis. | Compare program, process or system to established standards |
| **Benefits** | May or may not benefit current subjects; intended to benefit future patients. | Directly benefits a process, system or program; may or may not benefit patients. |
| **Risks** | May put subjects at risk. | Does not increase risk to patients, with exception of possible patients' privacy or confidentiality of data. |
| **Endpoint** | Answer a research question. | Improve a program, process or system. |
| **Publication/ Presentation** | Investigator obliged to share results. | Practitioners encouraged to share systematic reporting of insights. |

**CHECKLIST**

| CRITERIA | YES | NO |
|---|---|---|
| 1) Is the project primarily designed to test a specific hypothesis or answer a specific quantitative or qualitative question to contribute to generalizable knowledge outside of the Torrance Memorial Health System? | R | QI |
| 2) Does the project involve a comparison of multiple sites and/or control groups? | R | QI |
| 3) Is the project designed to support generalizations that go beyond the particular population the sample is being drawn from? | R | QI |
| 4) Are patients or providers randomized into different intervention groups in order to enhance confidence in differences that might be obscured by nonrandom selection? | R | QI |
| 5) Does the project impose any additional risks or burdens on participants beyond what would be normally expected or normally experienced during the course of care, program participation or role expectations? | R | QI |
| 6) Is the primary purpose of the project to produce the kind of results that could be published in a research journal? | R | QI |
| 7) Is there funding from an external organization based on support to carry out the proposed activity? | R | QI |
| 8) Does the project seek to test interventions, clinical practices, or treatments that are not standard (neither consensus-based, nor evidenced-based)? | R | QI |
| 9) Will project participants also likely be among those who might potentially benefit from the result of the project as it proceeds? | QI | R |
| 10) Is the project intended to develop a better practice within the Torrance Memorial hospital setting? | QI | R |
| 11) Would this project still be done at your site even if the results might not be applicable anywhere else? | QI | R |
| 12) Is the current project part of a continuous process of gathering or monitoring data within an organization? | QI | R |

*If the project is similar to both definitions, then the project is research.*

**R** = Research

**QI** = Quality Improvement