

**QUALITY IMPROVEMENT PROPOSAL TEMPLATE**

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| **Full project title** |
| **Name(s), Title(s), and Department of project leader** |
| **Proposal version number and version date** |

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| **Revision History** | | |
| **Version No.** | **Version Date** | **Description** |
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**TABLE OF CONTENTS**

**Project Overview ………………………………………………………………………………………………..#**

**Objectives ……………………………………………………………………………………………………….#**

**Methodology …………………………………………………………………………………………………….#**

**Data Collection ………………………………………………………………………………………………….#**

**Analysis ………………………………………………………………………………………………………….#**

**References / Bibliography ………………………………………………………………………………………#**

**DEFINITIONS**

**Human Subject**: According to 45 CFR 46 , a human subject is "a living individual about whom an investigator (whether professional or student) conducting research:

* Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
* Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens."

**Research**: A clinical investigation or systematic investigation, including research development, testing and evaluation, designed to develop or contribute to *generalizable knowledge.*

**Generalizable Knowledge:** Knowledge from which general conclusions will be drawn. A study that is designed to develop or contribute to Generalizable Knowledge is one that is designed and intended to draw conclusions, inform policy or generate generalizable findings.

**Quality Improvement (QI)** is the scenario where an activity is specifically initiated with the goal of improving and established standard. QI projects involve systematic, data-guided initiatives or processes designed to improve clinical care, patient safety, health care operations, services and programs or for developing new programs or services (e.g. teaching evaluations, patient/employee service surveys). QI is intended to use experience to identify effective methods, implement the methods broadly, and evaluate the immediate impact or effect of the implemented changes.

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| **QUALITY IMPROVEMENT CHECKLIST** | | |
| **Instructions:** Answer **YES** or **NO** to each of the following statements about your project. | **YES** | **NO** |
| 1. The intent of the project is to improve the process or delivery of care while decreasing inefficiencies within a specific health care setting as already established/accepted. |  |  |
| 1. The specific aim is to improve performance on a specific service or program and **is part of usual care.** All participants will receive standard of care. |  |  |
| 1. The project is **not** designed to answer a research question or test a hypothesis and is **not** intended to develop or contribute to generalizable knowledge. |  |  |
| 1. The project design does **not** test a hypothesis, involve randomization, or utilize comparison or control groups. |  |  |
| 1. The project has **no** funding from federal agencies or research-focused organizations, and is not receiving funding for implementation research. |  |  |
| 1. The project will involve a sample of the population (patients/participants) ordinarily seen in the institution where the activity will take place. |  |  |
| 1. Adequate protections are in place to maintain confidentiality of the data to be collected and there is a plan for who can access any data containing participant identifiers. |  |  |
| 1. The risk to patients/participants is no greater than what is involved in the care they are already receiving OR participating in the activity can be considered acceptable or ordinarily expected when practice changes are implemented within a health care environment |  |  |
| 1. The project does not require accessing patient or employee records beyond your scope of practice or responsibility. If records are beyond the scope, then a supervisor has provided documentation allowing access to the records. |  |  |
| 1. If any aspect of this project is changed or procedures added that would impact answers to any of the above questions, you agree to submit changes for PHCIRB review and approval prior to implementation of these changes. |  |  |
| **NOTE**: If the answer to **ALL** of these questions is **YES**, the activity can be considered a Quality Improvement activity that does not meet the definition of research. If the answer to **ANY** of these questions is **NO**,the project may be research. | | |