**VCOM Institutional Review Board**

**Quality Assurance/Quality Improvement or Research Assessment Worksheet**

This is a guide to help you determine if a proposed activity meets the criteria for a Quality Assurance/Quality Improvement (QA/QI) project. Such projects do not need to be submitted to the IRB for review. **If this is a student-driven project, note that this determination is the sole responsibility of the faculty mentor.**

After completing the checklist, if you check any boxes in the research column, or if you have any question whether your project is human subjects research or QA/QI, you will need a formal determination from the VCOM IRB. Please complete and submit the **Research Determination Application Form or contact IRB Administration**.

| **Please check the appropriate box in each row.** | | |
| --- | --- | --- |
|  | **Research** | **QA/QI** |
| Purpose | To test a hypothesis OR to establish clinical practice standards where none are already accepted/established. | To assess or improve a process, program, or system OR to improve performance as judged by established/ accepted standards. |
| Starting Point | To answer a research question or test a hypothesis. | To improve performance in a specific department, unit or area. |
| Background | Identifies a specific deficit in scientific knowledge from the literature. | Describes the nature and severity of a special local performance gap. |
| Methods | Specific protocol defines the intervention, interaction and use of collected data and may include randomization of individuals to different groups. | Mechanisms of the intervention may change in response to ongoing feedback. |
| Methods 2 | May use qualitative or quantitative methods to make observations, make comparisons between groups or generate hypotheses. | Plan for intervention and analysis includes assessment of the system or process flow. |
| Benefits | Designed to contribute to generalizable knowledge and may or may not benefit subjects. | Designed to promptly benefit a local process, program or system and may or may not benefit patients. |
| Risks | May or may not put persons at risk. | By design, does not increase risk to persons, with exception of possible privacy or confidentiality concerns. |
| Participants | The activity will involve participants who may not be ordinarily seen, cared for, or work in the setting where the activity will take place. | The activity will only involve participants (patients or staff) who are ordinarily seen, cared for, or work in the setting where the activity will take place? |
| End Point | Answer a research question. | Promptly improve a local program, process and/or system. |
| Analysis | Statistically prove or disprove hypothesis. | Compare a program, process, system to an established set of standards. |

**Additional Information**

Sometimes those conducting a project are required to have authoritative determination of whether a project is or is not human subjects research that needs IRB review. An authoritative determination might be required as a condition of a training program or by a journal or conference prior to acceptance of a manuscript for publication or presentation. In such cases, please submit an application to the VCOM IRB.

Once the application is submitted, the IRB will send to you a Notice of Determination letter or will contact you if needed.

***What is QA/QI?***

The terms Quality Assurance and Quality Improvement refer to activities conducted to assess, analyze, and improve current processes of health care delivery in an institutional setting. QA/QI activities:

* Are typically observational and unobtrusive;
* Involve the collection and analysis of data to which the investigators have legitimate access through their institutional roles;
* Do not prevent or hinder the delivery of clinically indicated care to patients, nor impose additional risks or burdens (physical or psychosocial) on patients.

There is no regulatory definition of Quality Assurance/Quality Improvement (QA/QI). In the health care setting, these projects often are described as “systematic data-guided activities designed to bring about immediate (or nearly immediate) improvements in health care delivery.” These activities include the combined efforts of everyone to make changes that will potentially lead to better outcomes, better system performance, and better professional development. In medical institutions, QA/QI is a necessary, integral part of an institution’s operations.

The purpose of a QA project is simply to assure known quality. These projects are mechanisms to assure that the medical institution functions optimally. Such projects are usually for internal auditing purposes only. Examples include:

* Evaluation of direct patient care processes
* Collection of statistical data for monitoring and clinical performance assessment purposes
* Assessment of community-based outreach programs for delivery of health care.

The purpose of a QI project is to determine quality, improve services, and/or improve the provision of medical care. A QI project is generally applied within a defined institutional setting, often a single department or division, and is usually intended to motivate change of practice in a specific location. The intent is to evaluate and alter processes constituting the delivery of health care in the near future, with the expectation that the population of patients usually served in that location will benefit.

***What is Research?***

Research is defined by federal regulation as “a systematic investigation, including development, testing and evaluation, designed to develop and contribute to generalizable knowledge” (45 CFR 46.102(d)). Research also includes clinical investigations as defined by the FDA to be any experiment that involves a test article and one or more persons (21 CFR 56.102(23)(c)). Human Subject Research is governed by federal regulation, under IRB oversight. Research involving human subjects must have IRB review and approval.

***Clarifications for Publishing or Presenting***

QA/QI can be published or presented; however, the project should not be referred to as “research” in any publication or presentation. When QA/QI is published or presented, the intent is usually to discuss potentially effective models, rather than to develop or contribute to generalizable knowledge.

If the project was not submitted to the IRB for determination, the following statement may be included in the manuscript: “This project was undertaken as a Quality Improvement Initiative and as such does not constitute human subjects research.”

If the project was reviewed by the IRB and was determined not to be human subjects research, the following statement can be included in the manuscript: “This Quality Improvement Initiative was reviewed and determined to not meet the criteria for human subjects research by the Edward Via College of Osteopathic Medicine Institutional Review Board.”

If a journal requires a formal IRB determination letter, submit this form along with a brief project summary as a new project in IRBNet. The IRB will then send the PI a determination that the project is not research.

**Additional Considerations**

Further clarification may be gathered by considering the questions below.

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| --- | --- | --- |
| **If you answer “Yes” to either question below, then your project is likely to be research.** | **YES** | **NO** |
| 1. Will the project seek to test interventions that are beyond current science and experience, such as new treatments and/or does the project involve care practices, interventions, or treatments that are not standard (neither consensus-based, nor evidence-based)? |  |  |
| 1. Does your project utilize test subjects for new devices, products, drugs, or materials? |  |  |
| **If you answer “Yes” to either question below, then your project is likely QA/QI.** | **YES** | **NO** |
| 1. Does your project involve only service surveys issued or completed by your hospital/clinic patients, students or staff for the intent and purpose of improving services and programs of hospital/clinic or for developing new services or programs? |  |  |
| 1. Is the goal of this project to implement a new hospital process founded upon evidence-based practice from current literature? |  |  |