Memorial
GRADUATE MEDICAL EDUCATION

CLINICAL QUALITY IMPROVEMENT

Do I need an IRB?

The checklist below can be utilized to help determine whether your proposed activity is **Clinical Quality Improvement/Measurement** that does not need IRB review, or **Quality Improvement Research** which does require IRB review. If necessary, review this checklist with the GME Clinical Research Manager or an Administrative Supervisor where the project will be conducted.

Examples of QI Projects NOT requiring IRB review:

- Reviewing pharmacy records to determine whether certain medications can be switched from IV to oral formulations in order to minimize risks and reduce costs.
- Implementing a safety assessment in a clinic seeing geriatric patients, in order to recommend/initiate appropriate referrals and services designed to keep older people safely in their homes.
- Monitoring radiation dosimetry in order to minimize radiation exposure in young patients likely to undergo multiple scans.
- Tracking "Door-to-Procedure" or "Door-to-Drug" turnaround times to develop ways to better meet accepted standards or goals.
- Examination of "no-show" at a clinic to ensure linkage to care and cost-effective utilization of staff time. This could include calling patients to ascertain why they did not make the scheduled visit.
- Implementation of a daily checklist to routinely assess "extubation readiness" in an ICU.
- Evaluation of characteristics of patients with catheter associated UTI's on a particular service to minimize this problem.

Publication of Results: The intent to publish the results of a project does not determine whether or not it needs IRB review. Publication of quality improvement does not necessarily mean it fits the definition of research. You may with to publish something if you believe others would be interested in learning about your activities without it being research. The publication should not refer to the activity as research and should make it clear that the publication is the result of a quality improvement activity. In addition, some QI projects are in fact better classifies as research even when there is no intention of disseminating or publishing the findings.

Helpful Links:

OHRP Quality Improvement Activities FAQs

Exempt Research Determination FAQs

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CLINICAL QUALITY IMPROVEMENT CHECKLIST		
Date:		
Brief Project Title:		
Faculty Advisor:		
Instructions: Answer **YES** or **NO** to each of the following statements about QI Projects.	**YES**	**NO**
The aim(s) of the project is to improve the process or delivery of care with established/accepted quality standards, or to implement change according to mandates of the hospital's Clinical Quality Improvement programs. There is no intention of using the data for research purposes.	☐	☐
The specific aim is to improve performance on a specific service or program in the hospital and **is part of usual care.** All participants will receive standard of care.	☐	☐
This project is **NOT** designed to answer a research question or test a hypothesis and is **NOT** intended to develop or contribute to generalizable knowledge.	☐	☐
The project does **NOT** follow a research design (e.g., hypothesis testing or group comparison, randomization, control groups, prospective comparison groups, cross-sectional, case-control). The project does **NOT** follow a protocol that over-rides clinical decision making.	☐	☐
The project involves implementation of established and tested quality standards and/or systematic monitoring, assessment or evaluation of the organization to ensure that existing quality standards are being met. The project does **NOT** develop paradigms or untested methods or new untested standards.	☐	☐
The project involves implementation of care practices and intervention that are consensus-bases or evidence-based. The project does **NOT** seek to test an intervention that is beyond current science and experience.	☐	☐
The project is conducted by staff where the project will take place, and involves staff who are working at, or patients who are seen at MHG.	☐	☐
The project has NO funding from federal agencies or research-focused organizations and is not receiving funding for implementation research.	☐	☐
The clinic, hospital, Research Oversight Committee (ROC) agrees that this is a QI project that will be implemented to improve the process or delivery of care (i.e., not a personal research project that is dependent upon the voluntary participation of colleagues, students and/or patients.).	☐	☐
If there is an intent to, or possibility of publishing your work, you and your faculty advisor are comfortable with the following statement in your methods section. *"This project was undertaken as a Quality Improvement Initiative at Memorial Hospital or X Clinic, and as such was not formally supervised by an Institutional Review Board per their policies."* **	☐	☐
If the answer to **ALL** of these questions is **YES**, the activity can be considered a Clinical Quality Improvement/Measurement activity that does not meet the definition of research. **IRB review is not required. Keep a dated copy of this checklist in your files.** If the answer to **ANY** of these questions is **NO**, the project will need to be submitted to an IRB for review.		

If project meets ALL of the criteria on this list and an editor or publication has concerns about, or disagrees with this statement, the IRB may be willing to write in support of your submission, clarifying the IRB policy/approach. **Contact Emily Foret, PhD, Manager, Clinical Research and GME for additional guidance.