CLINICAL QUALITY IMPROVEMENT/MEASUREMENT CHECKLIST

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. Consider consulting the IRB on challenging projects, for example those involving international sites, vulnerable populations, sensitive content, medical errors, or monetary incentives that are not hospital-wide. If necessary, review this checklist with the appropriate Department Chairperson or Administrative Supervisor where your project will be conducted.

Examples of QI Projects **NOT** requiring IRB review:

- Evaluation of characteristics of patients with catheter-associated UTI's on a particular service to minimize this problem.
- Implementation of a daily checklist to routinely assess "extubation readiness" in an ICU.
- Examination of "no-shows" at a clinic in order to insure linkage to care and cost-effective utilization of staff time. This could include calling patients to ascertain why they did not make a scheduled visit.
- Tracking "Door-to-Procedure" or "Door-to-Drug" turnaround times to develop ways to better meet accepted standards or goals.
- Monitoring radiation dosimetry in order to minimize radiation exposure in young patients likely to undergo multiple scans for care.
- 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.
- Reviewing pharmacy records to determine whether certain medications can be switched from IV to oral formulations in order to minimize risks and reduce costs.

Publication of Results: The intent to publish the results of a project does not determine whether or not it needs IRB review. Publication of a quality improvement project does not necessarily mean it fits the definition of research. You may wish 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 classified as research even when there is no intention of disseminating or publishing the findings.

External Funding: If your project is funded by an external research grant you should submit it for IRB review, as it is likely the funding agency is considering your project, or a part of it, research. If your project is funded by some other external entity, but not as a RESEARCH grant (e.g., foundation or individual philanthropy), send the grant title, funder, PI and a one paragraph summary of your project to Melissa Abraham PhD, IRB Chair. She can assist you in determining whether the project should be formally reviewed by the IRB.

Additional References:

PHRC Guidance: Review of Quality Measurement Initiatives:
http://healthcare.partners.org/phsirb/qmeasure.htm
OHRP Quality Improvement Activities – FAQs: http://answers.hhs.gov/ohrp/categories/1569

CLINICAL QUALITY IMPROVEMENT CHECKLIST		
Date:		
Division:		
Project Leader:		
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.	☐	☐
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.	☐	☐
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 interventions that are consensus-based 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 the Partners institution.	☐	☐
The project has **NO** funding from federal agencies or research-focused organizations, and is not receiving funding for implementation research (see External Funding on pg 1).	☐	☐
The clinical practice unit (hospital, clinic, division, or care group) 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 your colleagues, students and/or patients).	☐	☐
If there is an intent to, or possibility of publishing your work, you and your Department/QI Oversight group are comfortable with the following statement in your methods section: *"This project was undertaken as a Quality Improvement Initiative at X hospital or clinic, and as such was not formally supervised by the Institutional Review Board per their policies."* **	☐	☐
ANSWER KEY: 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 must be submitted to the IRB for review.		

If projects meet **ALL of the criteria on this list and an editor or publication has concerns about, or disagrees with this statement, the IRB is willing to write in support of your submission, clarifying the IRB policy/approach (contact Elizabeth L. Hohmann MD, Director and Chair, Partners Human Research Committee).