**Is My Project “Human Subject Research?”**

**RESEARCH INFORMATION AND DETERMINATION FORM**

This form is intended for in-house medical residents, clinical staff, and other individuals who are seeking to conduct projects at McLeod Health that may involve patients or patient data. It is designed to provide you with relevant information and help you to determine whether your project meets the standards for human subject research, which requires submission to the Institutional Review Board (IRB). In addition to utilizing this form, it is recommended that you discuss any potential project with your supervisor and/or the IRB Coordinator for further guidance.

**Common Terms and Acronyms**

* **Quality Assessment/Assurance (QA):** These are activities designed to determine whether aspects of medical practice are being performed in line with established standards. They may or may not reveal the need for quality improvement initiatives.
* **Quality Improvement (QI):** These are systematic, data-guided activities designed to bring about immediate improvements in health care delivery, such as better patient outcomes, better system performance, and better professional development.
* **Practice-Based Learning and Improvement (PBLI) project:** One of the ACGME requirements for residents, PBLI projects typically involve a systematic analysis of medical practice using QA/QI methods and the implementation of changes with the goal of practice improvement. Based on this definition, most PBLI projects can be labeled interchangeably as QI projects.
* **Human Subject Research (HSR):** This is a systematic investigation, including research develop-ment, testing, and evaluation, designed to develop or contribute to generalizable knowledge. It involves living individuals about whom an investigator: 1) obtains information or biospecimens through interaction/intervention with the individuals and studies such info or biospecimens; or 2) generates, obtains, uses, studies, and/or analyzes identifiable private information or identifiable biospecimens.

**How are QI/PBLI and HSR related?**

The definitions above reveal certain commonalities among these activities. For example, both QI/PBLI and human subject research involve systematic investigations. They both include data collection and analysis. When done well, both employ scientific rigor and methods. Most QI/PBLI activities also involve human participants to some degree.

**What are the differences between QI/PBLI and HSR?**

Despite these similarities, QI/PBLI activities and human subject research also differ in important ways. Many of these are listed in the table on the following page. Yet, perhaps the most important difference is that, unlike QI/PBLI activities, all human subject research must receive the review and approval of a federally registered IRB (unless eligible for exemption). **If your project involves or may possibly involve human subject research, it must be submitted to the McLeod Health IRB.**

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|  | **Research** | **QI/PBLI** |
| **Purpose** | To create new knowledge or to establish clinical practice standards where none exist | To implement established knowledge with the goal of improving a process, program, or performance according to accepted standards |
| **Process** | Often conducted on top of or independent of routine care | Conducted as part of ongoing care delivery |
| **Require-ments** | Subjects do not have an obligation to participate | Participation is necessary as part of care |
| **Risks/Burdens** | May put subjects at risk | No increased risk to patients, except perhaps some possible loss of confidentiality/privacy |
| **Analysis** | Results typically known only after study completion | Results continuously monitored throughout the process |
| **Benefits** | May benefit current subjects, but mainly intended to benefit future patients | Aims to directly benefit systems, patients, or populations in real time |

*Note: Occasionally, projects may be accurately classified as both QI/PBLI and human subject research (e.g. when patients are randomized between two accepted standards to determine best practice at a particular institution). Any such projects would also require submission to and approval from the IRB.*

Examples of quality improvement initiatives (non-research) for clinical or administrative purposes are:

* A radiology clinic creates a database to help monitor and forecast radiation dosimetry. This practice has been demonstrated to reduce over-exposure incidents in patients having multiple procedures. Patient data is collected from medical records and entered into the database, which is later analyzed to determine whether overexposures have decreased as expected.
* A group of affiliated hospitals implements a procedure known to reduce pharmacy prescription error rates. Authorized personnel collect prescription information from medical charts to assess adherence to the procedure and determine whether error rates have decreased as expected.
* As part of routine standard of care, a clinic primarily utilized by geriatric patients implements a widely accepted capacity assessment in order to identify patients requiring special services and staff expertise. Patient charts will later be audited to determine whether the assessments are successfully identifying all appropriate patients. The clinic plans to implement additional staff training if it finds that the assessments are not being administered routinely and correctly.

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| **QI/PBLI or HSR Determination****NOTE:** If your planned project will be prospective in nature (defined here as involving interactions with patients and/or the use of data that is not presently available), it is strongly recommended that you submit a project outline or summary to the IRB Office instead of utilizing this checklist.Respond to the following statements about your project with either “True” or “False.” |
| **1.** | **The purpose of my project is to improve performance of a specific service or program at McLeod and will be part of usual care.** | **[ ]** **True** | **[ ]** **False** |
| **2.** | **My project involves the implementation of established and tested quality standards and/or systematic monitoring, evaluation, or assessment to ensure existing quality standards are being met at McLeod. My project does NOT employ any untested methods or standards.** | **[ ]** **True** | **[ ]** **False** |
| **3.** | **Multiple cohorts will NOT be used and there will be NO random assignment of participants to compare outcomes.***Randomization and/or multiple cohorts imply an experimental approach; thus, projects employing these methods are typically classified as research.* | **[ ]** **True** | **[ ]** **False** |
| **4.** | **My project will NOT be conducted with the intent to apply the knowledge gained from its results to other programs/institutions outside McLeod.***A plan to apply results to other programs outside the original institution implies the intent to contribute to generalizable knowledge (a criterion of research).* | **[ ]** **True** | **[ ]** **False** |
| **5.** | **Reasonable measures are in place to assure participant confidentiality.***Collecting/analyzing de-identified data supports participant confidentiality. If the data to be accessed includes patient identifiers, confidentiality is not assured.* | **[ ]** **True** | **[ ]** **False** |
| **6.** | **The conduct of my project poses no more than minimal risk to participants.***Minimal risk is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.* | **[ ]** **True** | **[ ]** **False** |
| **7.** | **If I decide to present or publish the results of my project outside McLeod\*,I will characterize my work as a quality improvement (QI) or practice-based learning and improvement (PBLI) project, NOT as “human subject research.”***Consider including this or a similar statement in your Methods section: “This project was conducted as a quality improvement initiative and was not formally supervised by the McLeod Health Institutional Review Board per their policies.”* | **[ ]** **True** | **[ ]** **False** |

**If you answered “False” to any of the statements above, your project may be human subject research and should be submitted to the McLeod Health IRB.** For submissions assistance, or if you need any help determining whether your project is actually HSR, please contact the IRB Coordinator at 843-777-2013.

**\*Reminder:** All presentations and publications referencing MRMC or any McLeod Health entity must be reviewed by the Communications and Public Information Office (CPIO) ahead of time. Please submit a request for review at least 30 days in advance of presenting or publishing your work. (The request form is located on the McLeod intranet; enter “CPIO” in the search box.)