**Institutional**

**Review**

**Board**

**Mercy College of Health Sciences: Institutional Review Board (IRB)**

**Quality Improvement and Human Subject Involvement Determination**

This form should be used only if you believe your study is a **quality improvement (QI) project**. This form must be filled out by the Principal Investigator (not a coordinator or sub-investigator) and submitted by email to [IRB@mchs.edu](mailto:IRB@mchs.edu).

\*If you are considering submitting your study for publication, please review the ***Possibility of Publishing Work*** question (#10) below. Also, consider taking your study through the Mercy College Institutional Review Board (IRB). Contact the [IRB@mchs.edu](mailto:IRB@mchs.edu) for questions.

Principal Investigator:

Email:

Phone Number:

Study Title:

IRB Reference #:

Study Site:

Co-Investigator, if applicable:

Full Project Name:

Main research site for this project:

**Project Description—Determining the need for IRB review of QI Projects**

The following questions may be helpful in determining whether a proposed activity is a QI project, which may or may not require an IRB review. If all of the questions below can be answered “Yes”, IRB review *may not be required*. If the answer to any of these questions is “No”, please consult with the IRB at [IRB@mchs.edu](mailto:IRB@mchs.edu) for assistance to determine if IRB review *may be required*.

Both research and quality improvement are systematic investigations that may involve human participants, but they differ in important ways. These questions, used to help differentiate the need for IRB review, are based on information adapted from *The Ethics of Using QI Methods to Improve Health Care Quality and Safety* (The Hastings Center, 2006)*.*

Updated: 4.13.2021

**Directions:** Answer yes or no to the **bolded statements** below by placing an “X” in the appropriate box. *(Wording in italics is for clarification only.)*

|  |  |  |
| --- | --- | --- |
| **Respond to Bolded Statements Below** | Yes | No |
| 1. **Purpose: The project is designed to implement knowledge, improve current practice using the best available evidence, assess a current process or program for improvement that is different from established/accepted standards.**   *In human subjects research, the purpose of the project is to develop or contribute to generalizable knowledge.* |  |  |
| 1. **Knowledge-Seeking: The knowledge sought is integral to ongoing management of health care delivery systems or improvement of current practices.**   *Knowledge-seeking is independent of routine care/practice and intended to answer a question or test a hypothesis.* |  |  |
| 1. **Study Design: Adaptive, iterative (process for arriving at a decision or a desired result by repeating rounds of analysis or a cycle of operations) design.**   *Human subjects research design follows a rigid protocol that remains unchanged throughout the research.* |  |  |
| 1. **Benefits: Study results will directly benefit a process, system or program; may or may not directly benefit patients.**   *Human subject research may or may not benefit current subjects; intended to benefit future patients/participants.* |  |  |
| 1. **Risks: Does not increase risk to participants, with exception of possible privacy or confidentiality of data.**   *Human subject research may put subjects at risk of harm.* |  |  |
| 1. **Participant Obligation: Participants are obligated to participate as a component of care or educational practice.**   *Human subject research participants are not obligated to participate and may leave a study at any time.* |  |  |
| 1. **End Result: Improve a program, process, or system.**   *Human subject research is conducted to answer a research question.* |  |  |
| 1. **Analysis: Assess a program, process or system to established standards.**   *Human subject research analysis statistically proves or disproves a hypothesis, or identifies perceptions and experiences through interviews, focus groups, and/or observations.* |  |  |
| 1. **Adoption: Results rapidly adopted into local care delivery or practice.**   *Human subject research adoption of results: speed of adoption/place of adoption is not a focus.* |  |  |
| 1. **Dissemination/Publication: Investigators are encouraged to disseminate systematic reporting of insights gained.**   *Human subjects research publication/presentation: Researchers are obliged/urged to share results.*  \*If you answered "yes" to the possibility of publishing your work, you agree to add the following statement in your *Methods* section. (In addition, you are encouraged to review the publication requirements of journals to which you may submit the manuscript, as they may require IRB Approval.):  *“This project was undertaken as a Quality Improvement Initiative at Mercy College of Health Sciences and was not formally supervised by the Institutional Review Board per their policies.”* |  |  |

**Study Documents**

Attach a detailed description of the Project:

Attach a copy of all data collection tools (i.e. surveys, spreadsheets, etc.):

**Investigator's Assurance and Signature**

I am submitting this form in accordance with the policies of the Mercy College of Health Sciences IRB. I understand that I cannot initiate any changes in my approval protocol before I have received approval (expedited or full board review) and/or complied with all contingencies made in connection with that approval.

Upon approval by the IRB, this Amendment/Revision will, along with all existing approved materials, constitute a full and accurate description of the research study I am conducting.

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\*If there are any questions regarding your study please contact [IRB@mchs.edu](mailto:IRB@mchs.edu) for further information.