UMES IRB Quality Improvement Determination Worksheet for Investigators

This worksheet should be used to assist you in determining if your project is Quality Improvement versus Human Subjects Research. For each characteristic, please select the statement (Statement 1 or 2) that describes your project. Once you have completed this worksheet, please send it to the UMES IRB Chairperson for review and determination. Do not commence your study until a determination is made by the IRB Chairperson.

Summary

Please provide a summary of your project addressing the purpose of the study, who will be involved in the study, what will be gathered from the participants, how the information will be gathered, and any risks/benefits to the participants. Also, please indicate how the information gather will be utilized. Please limit your response to less than one page.

Purpose

Statement 1: This project is designed to develop or contribute to generalizable knowledge.

Statement 2: This project seeks to implement knowledge, assess a process, improve a program or delivery of care with consideration of established and or accepted standards.

Starting Point

Statement 1: This study is intended to answer a question or test a hypothesis. This study is independent of routine care.

Statement 2: This study is important to ongoing management of a program or system, including healthcare delivery systems.

Design

Statement 1: This study will follow a specific protocol designed to answer a discrete research question or set of questions.

AND/OR

Statement 1: This study intends to develop and evaluate a concept or process which can then be generalized.

AND/OR

Statement 1: This study will develop or evaluate a device or tool.

Statement 2: This study is adaptive and iterative.

Benefits

Statement 1: This study may or may not benefit the subjects and is intended to benefit future individuals.

Statement 2: This study has the potential to directly benefit a process, system or program yet it may not benefit individuals.

Risks

Statement 1: This study may impose minimal or greater than minimal risks to subjects.

Statement 2: This study does not impose an increased risk with the exception of privacy or confidentiality.

Endpoint

Statement 1: This study will answer a research question.

Statement 2: This study will improve a program, process or system.

Analysis

Statement 1: The analysis of this study will prove or disprove a hypothesis.

Statement 2: The analysis of this study will compare programs, processes, or systems to established standards or best practices.

Adoption of Results

Statement 1: This study is intended to contribute to generalizable knowledge.

AND/OR

Statement 1: The results of this study may be published in scientific journals or shared via presentations.

Statement 2: The results of this study will be used locally.

AND/OR

Statement 2: The results of this study may be shared.

Publication and or Presentation

Statement 1: The investigator is required to share results.

Statement 2: The investigator is encouraged to share insights.