Research Compliance Office
http://ors.umkc.edu/research-compliance
University of Missouri - Kansas City
5319 Rockhill Road
Kansas City, Missouri 64110-2499
816 235-5927 (Compliance Office)

Screening Checklist for Quality Improvement (QI) Projects

This checklist will help you determine whether a proposed project is in fact QI or potentially human subjects research.

Consideration	Question	Yes ✓	No ✓
PURPOSE	Is the primary aim or motive of the project either to: ☐ Improve care **right now** for the next patient seen? **OR** ☐ Improve operations or efficiency?		
RATIONALE	Is there sufficient evidence for, or acceptance of, this mode or approach to support implementing this activity or to create practice change, based on: ☐ literature, ☐ consensus statements, or ☐ consensus among clinician team?		
METHODS 1	Are the proposed methods flexible and customizable, and do they incorporate rapid evaluation, feedback and incremental changes?		
METHODS 2	Do the methods include any of the following? ☐ Control group ☐ Randomization ☐ Fixed protocol		
RISK	Is the risk related to the project minimal and no more than usual care (including the unavoidable minimal risk in implementing any changes made in processes of care)?		
PARTICIPANTS	Will the activity only involve participants (patients, parents) who are ordinarily seen, cared for, or work in the setting where the activity will take place?		
FUNDING	Is the project funded by any of the following? ☐ An outside organization with an interest in the results ☐ A manufacturer with an interest in the outcome of the project relevant to its products ☐ A non-profit foundation that typically funds research ☐ Internal research accounts		

Research Compliance Office
http://ors.umkc.edu/research-compliance
University of Missouri - Kansas City
5319 Rockhill Road
Kansas City, Missouri 64110-2499
816 235-5927 (Compliance Office)

If all of the check marks are inside the shaded blue boxes, then the project is very likely QI and not human subjects research. Projects that are not human subjects research do not need review by the IRB. If you need documentation of Not Human Subjects Research submit an application in eCompliance for a Human Subjects Research Determination.

For more guidance about whether the activity meets the definition of Human Subjects Research see https://ors.umkc.edu/services/compliance/irb/not-human-subjects-research.html

Characteristics of a QI projects that do not determine the need for IRB Review:

- Intent to publish – both QI and research may be published.
- Process of data collection – both QI and research may include prospective or retrospective data collection and may collect data on living/deceased individuals.

Clarifications for publishing QI work:

- Do not refer to QI projects as research in publications or presentations.

- If the project was not submitted to the IRB for determination, the following statement may be included in the manuscript:

"This project was undertaken as a Quality Improvement Initiative and as such does not constitute human subjects research."

- If the project was reviewed by the UMKC Research Compliance Office and was determined not to be human subjects research, the following statement can be included in the manuscript:

"This Quality Improvement Initiative was reviewed and determined to not meet the criteria for human subjects research by the University of Missouri Kansas City Research Compliance Office."