Quality Improvement (QI) Projects and IRB Review

QI activities oftentimes occupy an uncertain territory between clinical care and research. Although most QI activities involve a systematic investigation of some question of interest, many do not involve research as defined in the federal regulations for the protection of human subjects (45 CFR 46). In other cases, QI activities are designed to accomplish both a research purpose as well as a non-research purpose and IRB review is required. The following chart formulates some criteria that may be helpful in determining whether a QI project involves a research component and must be reviewed under the regulations for the protection of human subjects:

QI projects may include a research component if:	**QI projects do not include a research component if:**
▪ One purpose of the project is to develop generalizable results by testing a hypothesis OR by establishing a clinical practice standard where none exists	▪ The only purpose of the project is to assess or improve a process, program, or system OR improve performance as judged by established/accepted standards
▪ Study procedures involve applying a new intervention that is beyond current standard practice	▪ The only procedures involve standard practices, interventions or treatments
▪ Study procedures involve randomizing subjects into different intervention groups	▪ The only study procedures involve observing or comparing interventions that are already being done
▪ The project imposes risks or burdens to patients beyond those associated with the standard of practice	▪ The project does not impose additional risks on patients, with the exception of privacy/confidentiality concerns
▪ One outcome sought is to generate an analysis that can be applied to other programs, processes or systems	▪ The only outcome sought is an improvement in a program, process, or system