University of Kentucky (UK) Research vs. Quality Assurance/Improvement (QA/QI) Guidance

- The Department of Health and Human Services (DHHS), Office of Human Research Protections (OHRP), federal regulations that govern human subjects research (45 CFR 46) requires research with human subjects to be reviewed and approved by an Institutional Review Board (IRB) prior to initiation.

- QA/QI projects identify specific services, protocols, practices, processes, or outcomes within a department, program or facility for improvement. The main goal of the project is to improve patient care, a program or service. The intent to publish or present is generally not presumed at the outset; dissemination of information may occur in quality improvement publications or presentations.

- To determine whether a project constitutes research or QA/QI can be challenging. The IRB does not have the authority to retrospectively review a protocol or provide retroactive approval. It is therefore important to determine whether an activity meets the criteria for human subjects research or a QA/QI initiative **BEFORE** the activity is initiated.

- In some instances, QA/QI activities are designed to accomplish a research purpose, as well as the purpose of improving the quality of care. In such cases, federal human subjects regulations (45 CFR 46) apply and IRB review and approval must be in place **BEFORE** project initiation. For example, activities where data are gathered for improvement of a program, service or healthcare operations AND to generalize the results across institutions/hospitals/practices should be viewed as research.

- The intent to publish is an insufficient criterion on it's own, to determine whether a QA/QI activity constitutes research. Generalization of novel findings typically meets the definition of research.

- QA/QI activities with the express purpose of prospectively implementing a change in practice, which will later be evaluated through outcomes research, qualifies as human subjects research. Prospective collection of identifiable patient or subject- level data for future research is considered human subjects research, regardless of whether the institution that collects the data will de-identify the data before analysis.

- Failing to accurately determine whether an activity is research versus QA/QI could potentially jeopardize:
    - the safety, welfare, and/or rights of participants
    - an investigator and/or the Institution's ability to conduct research
    - an investigator and/or the Institution's ability to receive federal funding
    - publication of results

UNIVERSITY OF KENTUCKY
RESEARCH VS QUALITY IMPROVEMENT ACTIVITIES

This table is intended to help delineate quality improvement/assessment activities from research projects involving human subjects which require submission to the IRB.

Please contact the Office of Research Integrity (ORI) at (859) 257-9428 for a determination regarding the need for IRB review of proposed activity.

	RESEARCH	QUALITY IMPROVEMENT
INTENT & DESIGN	Intent of project is to contribute to generalizable knowledge; may involve randomization of individuals to different treatments, regimens, or processes (e.g., experimentation with new, novel, untested intervention; testing hypotheses); funding from outside organizations with interest in use of results	Intent of project is to improve, based on existing evidence, a practice or process within a particular institution or ensure it confirms with expected norms; Not designed to develop or contribute to generalizable knowledge; generally does not involve randomization/prospective assignment to different practices or processes
MOTIVATION FOR PROJECT	Project occurs in large part as a result of individual professional goals and requirements (e.g., seeking tenure; obtaining grants); involvement in key project roles of researchers who have no ongoing commitment to improvement of institutional practice	Project occurs regardless of whether individual(s) conducting it may benefit professionally from conducting the project. Authority to impose corrective plan based on outcome of project
MANDATE	Activities not mandated by institution or program	Activity mandated by the institution or clinic as part of its operations
EFFECT ON PROGRAM OR PRACTICE EVALUATED	Findings of the study are not expected to directly affect institutional or programmatic practice	Findings are expected to directly affect institutional practice and bring about immediate change
POPULATION	Usually involves a subset of individuals - universal participation of an entire clinic, program, or department is not expected, participation is voluntary; generally, statistical justification for sample size used to ensure endpoints can be met (exception would be Cluster Randomization Trials)	Requires participation or information on all or most individuals receiving a particular treatment or undergoing a particular practice or process; exclusion of information from some individuals significantly affects conclusions
BENEFITS	Participants may or may not benefit directly – benefit, if any, to individuals incidental or delayed	Local participants expected to benefit directly from the results of the activities
RISKS	May put subjects at risk; based on type of questions posed	Does not increase risk to patients, with exception of possible patients' privacy or confidentiality
ANALYSIS	Hold analysis until data collection complete to avoid biasing interpretation of results	Analysis continuous - positive findings immediately implemented. Analysis of data enabled by legitimate access through institutional role.
DISSEMINATION OF RESULTS	Intent to publish or present generally presumed at the outset of project as part of professional expectations, obligations; dissemination of information usually occurs in research/scientific publications or other research/scientific fora; results expected to develop or contribute to generalizable knowledge by filling a gap in scientific knowledge or supporting, refining, or refuting results from other research studies	Intent to publish or present generally not presumed at the outset of the project; dissemination of information often does not occur beyond the institution evaluated; dissemination of information may occur in quality improvement publications/fora; provide benchmarks or base rates rather than to develop or contribute to generalizable knowledge; title should include reference to the quality improvement project
CLINICAL SETTINGS		
USE OF PLACEBO	Use of placebo and/or control may be planned	Comparison of standard treatments, practices, techniques, processes (randomization or placebo would NOT be used)
DEVIATION FROM STANDARD PRACTICE	May involve significant deviation from standard practice	Unlikely to involve significant deviation from standard practice

- Contact the UK ORI (859-257-9428) or submit a Not Human Subjects Determination Form (NHR) https://redcap.uky.edu/redcap/surveys/index.php?s=49C9CLPJHK to determine whether an activity is research versus QA/QI **BEFORE** initiating the project.

- For information on other activities which may require IRB review please see the "What Needs IRB Review" webpage https://www.research.uky.edu/office-research-integrity/what-needs-irb-review
- Quality Improvement FAQs from OHRP guidance http://answers.hhs.gov/ohrp/categories/1569