An instrument to differentiate between clinical research and quality improvement

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Instrument to Assess the Differences between QI and Clinical Research with Human Subjects

This table is intended to compare and contrast the general characteristics of quality improvement (QI) and clinical research activities and is for use by Institutional Review Boards (IRBs), administrative reviewers, investigators, and improvers. This table is intended to guide discussion among these individuals and is not intended to supplant the judgment of IRBs or local QI ethics review committees. Please start by considering these overarching questions:

1. Will the activities of this project occur within the standard of care? If NO, then proceed to IRB review.
2. Is there risk? If YES, use chart below to determine whether this project requires QI review or IRB review.
3. Is this project primarily intended to generate generalizable knowledge? If YES, proceed to IRB review.
4. Does this project involve vulnerable populations? If YES, use chart below to determine whether this project requires QI review or IRB review.

For each item, choose the column to which the project most closely relates—QI or research. You may only choose one answer. Leave the item blank if neither choice applies.

Attribute	*Quality Improvement*	*Clinical Research with Human Subjects*
Intent and Background	☐ Describes the nature and severity of a specific local performance gap	☐ Identifies a specific deficit in scientific knowledge from the literature
	☐ Focus is to improve a specific aspect of health or health care delivery that is currently NOT consistently and appropriately being implemented at this site	☐ Proposes to address or identify specific hypotheses in order to develop new knowledge or advance existing knowledge
Methods	☐ Mechanisms of the intervention are expected to change over time (i.e., an iterative activity) in response to ongoing feedback	☐ Specific protocol defines the intervention, interaction, and use of collected data and tissues, plus project may rely on the randomization of individuals to enhance confidence in differences
	☐ Plan for intervention and analysis includes an assessment of the system (i.e., process flow diagram, fishbone, etc)	☐ May use qualitative or quantitative methods to make observations, make comparisons between groups, or generate hypotheses
	☐ Statistical methods evaluate system level processes and outcomes over time with statistical process control or other methods	☐ Statistical methods primarily compare differences between groups or correlate observed differences with a known health condition
Intended Benefit	☐ Intervention would be considered within the usual clinician-patient therapeutic relationship	☐ Intervention, interaction, or use of identifiable private information occurs outside of the usual clinician-patient therapeutic relationship
	☐ Direct benefit to participants is indicated (e.g., for the decrease in risk by receiving a vaccination or by creating a safer institutional system)	☐ Direct benefit to each individual participant or for the institution is not typically the intent or is not certain
	☐ Potential local institutional benefit is specified (e.g., increased efficiency or decreased cost)	☐ Potential societal benefit in developing new or advancing existing generalizable knowledge

Attribute	*Quality Improvement*	*Clinical Research with Human Subjects*
Risk	☐ Risk is to privacy or the confidentiality of health information	☐ Risks may be minimal, but may include physical, psychological, emotional, social, or financial risks, as well as risk to privacy or the confidentiality of health information from participation in the project
	☐ Risk may be described as higher for patients by not participating in this activity	☐ The informed consent process describes the risks to participants, who individually and voluntarily decide whether to participate or an IRB grants an alteration or waiver of the consent process
Applicability of Results	☐ Implementation is immediate so that review of results occurs throughout the process and may be used for next QI activity	☐ Results and analysis may be delayed or periodic throughout the duration of the project, except to protect patient safety. The results will primarily be used to inform further investigations, but may be implemented directly into clinical practice.
	☐ Extrapolation of results to other settings is possible, but not the main intent of the activity	☐ Results are intended to generalize beyond the study population
Sharing & Disseminating	☐ System level outcomes, processes, refinement of the intervention, and the applicability of the intervention in specific settings/contexts may be shared through peer-reviewed publication and presentation outside the institution.	☐ It is expected that results will be published or presented to others through a peer-reviewed process

Interpretation

Any checkmarks (even one) in the "Clinical Research" column indicates that there are components of clinical research in the proposed activity. The IRB or local QI ethics review committee should initiate a discussion with the improver/investigator to clarify the proposal. If an activity such as public health practice, program evaluation, or quality improvement includes a research component, then IRB review should occur under current federal guidance and the policies of many institutions.

Explanation and Elaboration of Terms

1. **Vulnerable population.** Any study population that includes students, employees, children, pregnant women, prisoners, active military personnel, individuals who have impaired decision making capacity, or those who are educationally or economically disadvantaged.
2. **Intent.** The state of the investigator's mind that directs the activity.
3. **Quality improvement.** The combined and unceasing efforts of everyone—health care professionals, patients and their families, researchers, administrators, payers, planners, educators—to make changes that will lead to better patient outcome, better system performance, and better professional development.
4. **Clinical research.** A systematic investigation in a clinical setting designed to develop or contribute to generalizable knowledge (The Common Rule definition of research)