Institutional Review Board Trinity Health Of New England
QI vs Research Checklist

Quality Improvement vs. Research Checklist		
This table is intended to compare and contrast the general characteristics of quality improvement (QI) and clinical research activities. For each item, choose the column to which the project most likely relates- QI or Research. You may only select ONE answer. Indicate N/A for those sections that do not apply. Retain the completed assessment in your project files.		
Intent and Background		
	Quality Improvement	**Research with Human Participants**
1.	Describes the nature and severity of a specific performance gap. ☐ Yes ☐ No ☐ N/A	Identifies a specific deficit in scientific knowledge from the literature. ☐ Yes ☐ No ☐ N/A
2.	The focus is to improve a specific aspect of health or healthcare delivery that currently needs to be consistently and appropriately implemented at this site. (Maybe due to HCAHPS, Culture of Safety, and Engagement Surveys). ☐ Yes ☐ No ☐ N/A	Proposes to address or identify specific hypotheses to develop new knowledge or advance the current understanding. ☐ Yes ☐ No ☐ N/A
Methods		
	Quality Improvement	**Research with Human Participants**
3.	Mechanisms of the intervention are expected to change over time (i.e., iterative in nature) in response to ongoing feedback; adjustments are made as one progresses through the process to refine. ☐ Yes ☐ No ☐ N/A	The specific protocol defines the intervention, interaction, and use of collected data and tissues, plus the project may rely on the randomization of individuals to enhance confidence in differences. ☐ Yes ☐ No ☐ N/A
4.	The plan for intervention and analysis includes an assessment of the system (i.e., process flow diagram, fishbone, etc.). ☐ Yes ☐ No ☐ N/A	May use qualitative and quantitative methods to make observations and compare groups to answer the hypotheses. ☐ Yes ☐ No ☐ N/A
5.	Statistical methods evaluate system-level processes and outcomes over time with statistical process control or other practices. ☐ Yes ☐ No ☐ N/A	Statistical methods primarily compare differences between groups or correlate observed differences with a known health condition. ☐ Yes ☐ No ☐ N/A

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Intended Benefit		
	Quality Improvement	**Research with Human Participants**
6.	Intervention would be considered within the usual clinician-patient therapeutic relationship. ☐ Yes ☐ No ☐ N/A	Intervention, interaction, or use of identifiable private information occurs outside the clinician-patient therapeutic relationship. ☐ Yes ☐ No ☐ N/A
7.	Direct benefit to participants is indicated (e.g., for the decrease in risk by creating a safer institutional system). ☐ Yes ☐ No ☐ N/A	Direct benefit to each participant or for the institution is not typically the intent or is not certain. ☐ Yes ☐ No ☐ N/A
Risk		
	Quality Improvement	**Research with Human Participants**
9.	Risk is to the privacy or the confidentiality of health information as it relates to the responsibilities of being a covered entity (Health care system). ☐ Yes ☐ No ☐ N/A	The risk 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. ☐ Yes ☐ No ☐ N/A
10.	The risk may be higher for patients if the institution or group/staff does nothing. ☐ Yes ☐ No ☐ N/A	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. ☐ Yes ☐ No ☐ N/A
Applicability of Results		
	Quality Improvement	**Research with Human Participants**
11.	Intent to disseminate results is generally not presumed at the outset of the project; dissemination often does not occur beyond the institution evaluated; the intent is to suggest potentially effective models, strategies, and assessment tools or provide benchmarks rather than to develop or contribute to generalizable knowledge. ☐ Yes ☐ No ☐ N/A	Intent to disseminate results generally presumed at the outset of the project as part of professional expectations and obligations; 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. ☐ Yes ☐ No ☐ N/A
12.	Extrapolating results to other settings is possible, but only some of the activity's intent. ☐ Yes ☐ No ☐ N/A	Results are intended to generalize beyond the institution and to a specific study population. ☐ Yes ☐ No ☐ N/A

Interpretation:

Any checkmarks (even one) in the " Research" column indicate that there are components of research in the proposed activity. If training such as public health practice, program evaluation, or quality improvement includes research, then IRB review should occur under current federal guidelines and IRB policies. Note: consider the journal requirements regarding IRB reviews/determinations if a publication is anticipated. IRB reviews cannot occur once the data has been gathered. Any IRB review must be prospective BEFORE any data collection work commences.

Explanation and Elaboration of Terms:

- Vulnerable Population: Any study population that includes students, employees, children, pregnant women, prisoners, active military personnel, individuals who have diminished decision-making capacity, or those who are educationally or economically disadvantaged.
- Intent: The state of the investigator's mind that directs the activity.
- Quality Improvement: The combined and unceasing efforts of everyone – health care professionals, patients, and their families, researchers, administrators, payers, planners, and educators – to make changes that will lead to better patient outcomes, better system performance, and better professional development.
- Research: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. A human participant is a "living individual about whom an investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with the individual, or (2) Identifiable private information" (Common Rule definition of research).

Contact Information:

Please contact the IRB if you have any questions:

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