

Saint Joseph's Health System – Institutional Review Board Quality Improvement vs Research Determination Checklist



A Member of Trinity Health

Title of Project: _____

Leader: _____ Department: _____ Institution: SJH Hospital Other: _____

This table is intended to provide a means to self-declare whether a project meets the definition of quality improvement (QI) or clinical research activities. For each item, choose the column to which the project most likely relates- QI or Research. You may only choose ONE answer. Indicate N/A for those sections that do not apply.

| Attribute | Quality Improvement | Research with Human Participants |
|------------------------------|--|---|
| Intent and Background | <input type="checkbox"/> Describes the nature and severity of a specific performance gap | <input type="checkbox"/> Identifies a specific deficit in scientific knowledge from the literature |
| | <input type="checkbox"/> 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 (may be as a result of HCAHPS, Culture of Safety, Engagement Surveys) | <input type="checkbox"/> Proposes to address or identify specific hypotheses in order to develop new knowledge or advance existing knowledge |
| Methods | <input type="checkbox"/> Mechanisms of the intervention are expected to change over time (i.e., an iterative in nature) in response to ongoing feedback; adjustments made as one progresses through the process to refine | <input type="checkbox"/> 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 |
| | <input type="checkbox"/> Plan for intervention and analysis includes an assessment of the system (i.e., process flow diagram, fishbone, etc.) | <input type="checkbox"/> May use qualitative and quantitative methods to make observations, make comparisons between groups to answer the hypotheses |
| | <input type="checkbox"/> Statistical methods evaluate system level processes and outcomes over time with statistical process control or other methods | <input type="checkbox"/> Statistical methods primarily compare differences between groups or correlate observed differences with a known health condition |
| Intended Benefit | <input type="checkbox"/> Intervention would be considered within the usual clinician-patient therapeutic relationship | <input type="checkbox"/> Intervention, interaction, or use of identifiable private information or specimens occurs outside the clinician-patient therapeutic relationship |
| | <input type="checkbox"/> Direct benefit to participants is indicated (e.g., for the decrease in risk by creating a safer institutional system) | <input type="checkbox"/> Direct benefit to each individual participant or for the institution is not typically the intent or is not certain. |
| | <input type="checkbox"/> Potential local institutional benefit is indicated (e.g., increased efficiency or decreased cost) | <input type="checkbox"/> Potential societal benefit in developing new or advancing existing generalizable knowledge |
| Risk | <input type="checkbox"/> 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)] | <input type="checkbox"/> 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 |

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|---------------------------------|---|---|
| | <input type="checkbox"/> Risk may be described as higher for patients if the institution or group / staff does nothing | <input type="checkbox"/> Informed consent describes the risks to participants, who individually and voluntarily decide whether to participate (consent could also be optional, such as with exempt research, or could be waived by the IRB) |
| Applicability of Results | <input type="checkbox"/> Implementation is immediate so that review of results occurs throughout the process and may be used for next QI activity | <input type="checkbox"/> 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 investigation |
| | <input type="checkbox"/> Extrapolation of results to other settings is possible, but not the main intent of the activity | <input type="checkbox"/> Results are intended to generalize beyond the institution and to a specific study population |

Interpretation

If any marks are on the research side, then submit your project to the IRB for review and determination (see the IRB website for forms and instructions). Retain the completed assessment in your project files if ALL of the marks are on the QI side. 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 IRB policies. **If a publication is anticipated then determine if the journal requires a formal IRB determination. IRB reviews cannot occur once the data has been gathered or analyzed. Any IRB review must be prospective, that is, BEFORE any data collection work commences.**

Explanation and Elaboration of Terms

- Vulnerable Population:** Generally a population that includes students, employees, children, prisoners, active military personnel, individuals who have diminished decision making capacity, those who are educationally or economically disadvantaged or others likely to be vulnerable to undue influence and/or coercion.
- Intent:** The state of the investigator's mind that directs the activity.
- Quality Improvement:** The combined and unceasing efforts of many – health care professionals, patients and their families, administrators, payers, planners, educators –to make changes that will lead to better patient outcome, 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 means a living individual about whom an investigator (whether professional or student) conducting research:
 - (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; **or** (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens (2018 (Revised) Common Rule definition of *Research* and *Human Subject*).

Evaluator: _____
Print Name
Signature
Date of Evaluation

Faculty/Supervisor: _____
Print Name
Signature
Date

This form was adapted from: Ogrinc, G., Nelson, W. Q., Adams, S. M., & O'Hara, A. E. (2013). An instrument to differentiate between clinical research and quality improvement. *IRB Ethics & Human Research*, 35(5).