Trinity Health

Quality Improvement vs Research Determination Checklist

Trinity Health – Michigan
Research Compliance Department

Project Title:		
Project Leader:	**Department:**	**Institution:**

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 attribute, make only ONE selection in the column to which the project most likely relates - QI or Research. Indicate **N/A** for those sections that do not apply.

Attribute	Quality Improvement	Research with Human Participants
Intent and Background	☐ Describes the nature and severity of a specific 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 (may be as a result of HCAHPS, Culture of Safety, Engagement Surveys)	☐ Proposes to address or identify specific hypotheses in order to develop new knowledge or advance existing knowledge
	☐ **N/A**	☐ **N/A**
Methods	☐ 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	☐ 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 and quantitative methods to make observations, make comparisons between groups to answer the 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
	☐ **N/A**	☐ **N/A**
Intended Benefit	☐ Intervention would be considered within the usual clinician-patient therapeutic relationship	☐ Intervention, interaction, or use of identifiable private information or specimens occurs outside the clinician-patient therapeutic relationship
	☐ Direct benefit to participants is indicated (e.g., for the decrease in risk 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 indicated (e.g., increased efficiency or decreased cost)	☐ Potential societal benefit in developing new or advancing existing generalizable knowledge
	☐ **N/A**	☐ **N/A**
Risk	☐ 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)]	☐ 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
	☐ Risk may be described as higher for patients if the institution or group/staff does nothing	☐ 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)
	☐ **N/A**	☐ **N/A**

This form was adapted from a publication entitled: An Instrument to Differentiate between Clinical Research and Quality Improvement, Ogrinc Greg; William A. Nelson; Susan M. Adams; and Ann E. O'Hara. IRB Ethics & Human Research. September – October 2013; Vol 35, Number 5.

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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 investigation
	☐ Extrapolation of results to other settings is possible, but not the main intent of the activity ☐ **N/A**	☐ Results are intended to generalize beyond the institution and to a specific study population ☐ **N/A**

Interpretation

- If **ALL** marks are in the **QI column**, RETAIN THIS COMPLETED ASSESSMENT in your project files. No submission to the IRB is required.
- If **any marks** are in the **research column**, you must submit an IRB Application with the required documents BEFORE any data collection work commences. **IRB review cannot occur once the data has been collected or analyzed for the purposes of research**.
- If an activity such as public health practice, program evaluation, or quality improvement *includes a research component,* then IRB review should occur prior to research conduct.

Explanation and Elaboration of Terms

1. **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.
2. **Intent:** The state of the investigator's mind that directs the activity.
3. **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 outcomes, better system performance, and better professional development.
4. **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 *(Common Rule definition of research).*
5. **Project Proposal** must **not** contain any terminology relating to research (i.e., investigator, investigation, research, study, testing, etc.)

Evaluator: _____

Typed or Printed Name *Signature & Date*

Faculty/Supervisor: _____

Typed or Printed Name *Signature & Date*

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