Trinity Health

Quality Improvement vs Research Determination Checklist

Trinity Health(TH) Michigan
Research Compliance Department (RCD)
Institutional Review Board (IRB)

Project Title

Quality Improvement/Assurance, Program Evaluation		Research	
PURPOSE ☐	Project activity is specifically initiated with a goal of improving/ understanding/evaluating local processes/practices related to patient care: experiences, operations, cost productivity, quality, or efficiency. (Proposal should not contain language relating to research, e.g. investigator, investigation, research, study, testing, etc.)	**PURPOSE** ☐	Facts will be gathered to test a hypothesis for a specific deficit identified in scientific knowledge to answer a question or test a hypothesis and develop or contribute to generalizable knowledge
METHODS ☐	Project methods are repetitive/flexible/customizable, allowing for rapid evaluation, feedback, and incremental changes. Design may or may not be systematic, usually does not involve randomization, control groups, or a fixed protocol.	**METHODS** ☐	Systematic design adhering strictly to the research protocol. May involve randomization, control groups, etc. Participant intervention, interaction, or use of their identifiable information/ specimens, and/or activities will occur outside of their usual care.
BENEFIT ☐	Patient, staff, providers, and institution may benefit from activity by decreasing risk/costs, increasing efficiency, safety, and quality of care.	**BENEFIT** ☐	Clinician, researcher, scientific community will benefit, and project participants benefit is unknown until end of project. Society may potentially benefit from the development of new or advancing existing generalizable knowledge. Results from the project will not directly benefit institutional practices or programs.
RISKS ☐	Project risks are minimal and would be no more than what would occur in patients usual care or practices, includes minimal risks that may be unavoidable when implementing processes of care changes, with the exception of possible privacy/confidentiality concerns. (Use or disclosure of PHI for activities under this column are described in the TH Notice of Privacy Practices provided to the patient at time of care.)	**RISKS** ☐	Participants may be placed at risk that are minimal and may sign an informed consent document. The minimal risks can include physical, psychological, emotional, social, or financial risks, as well as risk to privacy/confidentiality of health information from participation in the project
RESULTS ☐	Will directly impact the institutional processes or practices being quickly adopted into local care delivery. Dissemination of results will not be implemented beyond the institution. Publication of project results intention is to suggest potentially effective models and strategies rather than generalizable knowledge.	**RESULTS** ☐	Intent to disseminate assumed at the outset of the project and will usually not be disseminated right away. Are expected to develop or contribute to generalizable knowledge by filling a gap in the scientific literature.
➢ **If ALL** marks are on this side **No submission to the IRB is required**, you may self-declare the project meets the above criteria and file this document with the project files. If the project leader wishes to obtain an official letter from the IRB click link below and follow the submission instructions at your location.		➢ **If ANY** marks are on this side, **submit to the IRB BEFORE** any research activities commence including data collection.	

Click here for further information regarding the RCD/IRB, Research vs. Quality Improvement, IRB Policies, or Submission Instructions

Project Leader Printed Name	Project Leader Signature	Institution/Department	Date
Faculty/Supervisor Printed Name	**Faculty/Supervisor Signature**	**Institution/Department**	**Date**