

**Date:** \_\_\_\_\_

**Project Title:** \_\_\_\_\_

**Project Coordinator:** \_\_\_\_\_

**Department:** \_\_\_\_\_

**NOTE: All multi-institutional QI projects (e.g., CCHMC, TriHealth) require both Administrative Review and IRB approval.**
**If this project will affect other departments within TriHealth, are the stakeholders aware of how your project may impact them?      Yes      No**
**Does this project involve a vulnerable population?      Yes      No      If yes, an evaluation of provisions for additional protections for vulnerable populations may be necessary.**

Please answer the following questions to help determine if your project is QI or Research:	Yes	No
1. Is the intent of your project to improve the process or delivery of care with established/accepted quality standards, or to implement change according to mandates of TriHealth’s Clinical Quality Improvement programs and there is no intent of using the data for research purposes?		
2. Is the goal of your project to improve performance of a specific program or service within your department and is part of routine care?		
3. The intended outcome of your project is not to develop or contribute to generalizable knowledge?		
4. Does your project involve implementation of care practices and interventions that are evidence-based and the project does not seek to test an intervention that is beyond current science and experience?		
5. Is the project going to be conducted by departmental staff which provide care or are responsible for the practice change?		
6. Are the mechanisms of the intervention expected to change over time (i.e., iterative activity) in response to ongoing feedback?		
7. Does your plan for intervention and analysis include a QI methodology (i.e., Model for Improvement, the Breakthrough Series Model (BTS), PDSA, Six sigma, Process Flow Diagram, Fishbone, Root Cause Analysis, etc.)?		
8. Will the statistical methods evaluate system level processes and outcomes overtime with statistical process control or other methods?		
9. Is there a direct benefit to participants (e.g., for the decrease in risk by receiving a vaccination or be creating a safer institutional system)?		
10. Is the risk to patients/participants no greater that what is involved in the care they are already receiving OR can participating in the activity be considered acceptable or ordinarily expected when practice changes are implemented with a health care environment?		
11. Will implementation of the process be immediate so that review of results occurs throughout the process and may be used for the next QI activity?		
12. Your project has no funding from federal agencies?		
13. Your department head agrees that this is a QI project that will be implemented to improve the process or delivery of care (i.e., not a personal research project that is dependent upon the voluntary participation of your patients and co-workers.		

***If all the checkmarks are “YES” your project qualifies as QI and does not require Administrative Review or IRB approval. Any checkmarks (even one) in the “NO” column indicates there are components of research in the proposed activity and Administrative Review and IRB approval is required.***
**Project Coordinator Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**Department Chair Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_