The University of Tennessee at Chattanooga Institutional Review Board

Quality Improvement or Research Checklist*

In general, a quality improvement (QI) project does not require IRB review and approval because it is not research that is subject to the federal human subjects protection regulations. The following questions may be helpful in determining whether a proposed activity is a QI project and does not involve human subjects research. If all of the questions below can be answered as a Yes, IRB review is not required. If the answer to any of these questions is NO, please consult with the IRB for assistance since IRB review may be required.

Project Description	YES	NO
Purpose Is the activity intended to improve the process/delivery of care while decreasing inefficiencies within a specific health care setting?		
Scope Is the activity intended to evaluate current practice and/or attempt to improve it based upon existing knowledge?		
Evidence Is there sufficient existing evidence to support implementing this activity to create practice change?		
Clinicians/Staff Is the activity conducted by clinicians and staff who provide care or are responsible for the practice change in the institutions where the activity will take place?		
Methods Are the methods for the activity flexible and include approaches to evaluate rapid and incremental changes?		
Sample/Population Will the activity involve a sample of the population (patients/participants) ordinarily seen in the institution where the activity will take place?		
Consent Will the planned activity only require consent that is already obtained in clinical practice, and could the activity be considered part of the usual care?		
Benefits Will future patients/participants at the institution where the planned activity will be implemented potentially benefit from the project?		
Risk Is the risk to patients/participants no greater than 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 within a health care environment?		

*Adapted with permission from Duke University IRB, Sept 2018