

THIS FORM MUST BE TYPED
Submit One Copy to the IRB Office

QI#: _____

**East Tennessee Children's Hospital
Institutional Review Board (IRB)
1st Floor Nursing Administration Koppel Plaza
865.541.8290, Email: research@etch.com**

No data may be collected until you have received approval from the IRB

Quality Improvement / Process Improvement

1. Project Title

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2. Circle status: Faculty / Resident / Fellow

First Name:	Middle Initial:	Last Name:				
Degree(s):	M.D.	D.O.	Ph.D.	D.D.S	PharmD.	Other:
Department:						
Email:						
Cell Phone:						

3. Other Key Study Personnel or ___ NA

Anyone who may be listed on a publication/presentation must be listed on the application.

Name/Degree and SIGNATURE	Department / Division or Affiliation	Role In Project

4. **Definitions:**

Quality Improvement / Performance Improvement is utilized to assess or improve a process or system or to improve performance as judged by accepted standards where the knowledge benefits a process and may not benefit patients and creates a process / system that results in greater safety, efficiency or satisfaction.

Research is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Generalizable knowledge is information or findings that can be applied to populations or situations beyond those being immediately studied.

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or obtains identifiable private information.

5. ***The QI project must be submitted to the IRB as a research project if any of the following are true:***

- a. The intent is to use the data to contribute to generalizable knowledge,
- b. Participants are randomized to compare outcomes,
- c. The activities are not normally done as part of standard operating procedures,
- d. Results will be used to apply knowledge to other programs outside the institution,
- e. The project is subject to peer review (designed to be used outside of the institution),
- f. Anonymity of participants cannot be assured, or
- g. The activities involve more than minimal risk to participants.

6. Attach a written description of the proposed QI project below. Address the following:

- a. Statement of the Problem
- b. Project Aims
- c. Project Methods
- d. Data Collection Plan
- e. Timeline
- f. Evaluation Plan
- g. Privacy, Data Storage & Confidentiality Plan of PHI

Answer all questions below:

<p align="center">Project Description <i>Using the information above, answer the following questions:</i></p>	<p align="center">YES</p>	<p align="center">NO</p>
<p>Will the activity assess or improve a process, program, or system OR will it improve performance as judged by established/accepted standards?</p>		
<p>Is the activity intended to improve the process/delivery of care while decreasing inefficiencies within a specific health care setting?</p>		
<p>Is the activity intended to evaluate current practice and/or attempt to improve it based upon existing knowledge?</p>		
<p>Is there sufficient existing evidence to support implementing this activity to create practice change?</p>		
<p>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?</p>		
<p>Are the methods for the activity flexible and include approaches to evaluate rapid and incremental changes?</p>		
<p>Will the activity involve a sample of the population (patients/participants) ordinarily seen in the institution where the activity will take place?</p>		
<p>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?</p>		
<p>Will future patients/participants at the institution where the planned activity will be implemented potentially benefit from the project?</p>		
<p>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?</p>		

Project Description <i>Using the information above, answer the following questions:</i>	YES	NO
Does the activity involve research? See definition		
If you answered yes to the question above, does the research activity involve human subjects? See definition		

7. ATTACH DESCRIPTION, OBTAIN ALL SIGNATURES and Submit to the IRB Office

Signature of Faculty / Resident / Fellow	Date:
Signature of Department Chair	Date:
Typewritten Name of Department Chair:	

*Adapted with permission from the Duke University IRB, 04/30/2013