**THIS FORM MUST BE TYPED**

 **Submit One Copy to the IRB Office**

**University of Tennessee College of Medicine Chattanooga**

**Institutional Review Board (IRB)**

**Form J**

***If your project involves collecting data from Medical Records, a Form H must also be submitted requesting a Waiver of Authorization***

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

**Quality Improvement / Process Improvement**

1. **Project Title:** Click or tap here to enter text.

**2.** **Contact Information (please remember, PI’s for all projects must be a UTCOMC or Erlanger Faculty Member/Physician)**

|  |  |  |
| --- | --- | --- |
| First Name: Click or tap here to enter text. | Middle Initial: Click or tap here to enter text. | Last Name:Click or tap here to enter text. |
| Degree(s): M.D.[ ]  D.O.[ ]  Ph.D.[ ]  PharmD.[ ]  Nurse [ ]  Other:Click or tap here to enter text. |
| Department:Click or tap here to enter text. |
| Email:Click or tap here to enter text. |
| Phone:Click or tap here to enter text. |

**3.** **Other Key Study Personnel/ Faculty/Resident/Fellow/Student/Other 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** |
| --- | --- | --- |
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**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: Click all that are applicable.***

* 1. [ ] The intent is to use the data to contribute to generalizable knowledge,
	2. [ ] Participants are randomized to compare outcomes,
	3. [ ] The activities are not normally done as part of standard operating procedures,
	4. [ ] Results will be used to apply knowledge to other programs outside the institution,
	5. [ ] The project is subject to peer review (designed to be used outside of the institution),
	6. [ ] Anonymity of participants cannot be assured, or
	7. [ ] The activities involve more than minimal risk to participants.

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

1. Statement of the Problem
2. Project Aims
3. Project Methods
4. Data Collection Plan along with a Data Collection Spreadsheet
5. Timeline
6. Evaluation Plan
7. Privacy, Data Storage & Confidentiality Plan of PHI

**Answer all questions below:**

| **Project Description*****Using the information above, answer the following questions:*** | **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 |[ ] [ ]
| Will the activity assess or improve a process, program, or system OR will it improve performance as judged by established/accepted standards? |[ ] [ ]
| Is the activity intended to improve the process/delivery of care while decreasing inefficiencies within a specific health care setting? |[ ] [ ]
| Is the activity intended to evaluate current practice and/or attempt to improve it based upon existing knowledge? |[ ] [ ]
| Is there sufficient existing evidence to support implementing this activity to create practice change? |[ ] [ ]
| 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? |[ ] [ ]
| Are the methods for the activity flexible and include approaches to evaluate rapid and incremental changes? |[ ] [ ]
| Will the activity involve a sample of the population (patients/participants) ordinarily seen in the institution where the activity will take place? |[ ] [ ]
| 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? |[ ] [ ]
| Will future patients/participants at the institution where the planned activity will be implemented potentially benefit from the project? |[ ] [ ]
| 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? |[ ] [ ]

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

**UTCOMIRB Office**

|  |  |
| --- | --- |
| Signature of Faculty | Date: |
| Signature of Department Chair | Date: |
| Typewritten Name of Department Chair:  |
| Signature of IRB Chairman Date:  |
|  |

\*Adapted from UT Knoxville Graduate School of Medicine IRB