|  |  |  |
| --- | --- | --- |
| **THIS FORM MUST BE TYPED**  **Submit One Copy to the IRB Office** |  | **IRB QI#**:  **IRB Office will assign** |

**University of Tennessee Graduate School of Medicine**

**Institutional Review Board (IRB)**

**Quality Improvement / Process Improvement**

**Residents presenting QI/PI projects must submit this application form to the IRB prior to any data collection. Prospective IRB approval is required – this means requests for an IRB determination submitted to the IRB after data are collected will not receive an IRB determination/approval.**

**All personnel listed on this form must be identical to the personnel listed on the GME Travel Request Application. Do not submit a Travel Request without a valid IRB number.**

**1. Project Title**

|  |
| --- |
|  |

**2. Resident / Fellow Information**

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

**3.** **Other Key Study Personnel or \_\_\_** NA

**Anyone listed on the 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 through*** [***iMedRIS***](https://imedris.uthsc.edu/) ***as a research project if any of the following are true:***

* 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. Address the following:

1. Statement of the Problem
2. Project Aims
3. Project Methods
4. Data Collection Plan
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** |
| --- | --- | --- |
| 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? |  |  |
| **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