**Quality assessment and quality initiative (QA/QI)** clinical studies are usually involved with trying to assess the current state of medical care, or to determine the effect of an intervention to improve medical care. That description may well give one pause, as it seems that these words could just as easily be used to describe a retrospective or prospective trial. The distinction can at times be tricky, but the IRB is available to help.

Why should you care, anyway? Well, it actually becomes a big issue with regards to the level of review from the IRB. If the study is determined to be QA/QI, the only caveat is that when writing your abstract, presenting your results, or writing up your manuscript, you cannot refer to your study as “research”. You can call it a QA project, you can call it a QI investigation, you can call it a QA/QI protocol, just not a research study. For more information on this, or on QA/QI studies in general, please contact the IRB at 337-4345.

**Title**

(Descriptive title; keep it tight, no 100 word titles)

**Investigators:**

**Version Date** (e.g., the date the protocol was created):

**Background/Problem Statement:** List the reasons for the quality initiative/assessment. Describe the current state, as well as the reason for the intervention. Provide references from the literature or previous work in the area of interest if applicable.

***Example:***

*Medication error rates have become a growing concern for hospital systems, and are linked to complications and increased length of stay.1,2 In the United States, medication errors accounted for 200 million dollars in increased health care costs in 2012.3 Computerized physician ordering software has been promoted as one mechanism for reducing the rates of these errors.4*

*The medication error rate at General Hospital over the past year was 20%. In order to reduce this rate and increase patient safety, implementation of a computerized physician ordering system has been proposed.*

**Study Aim(s):** Identify the specific aim(s) for your study.

***Examples:***

*To determine the impact of the new medication ordering system on medication error rates at General Hospital at 3 months, 6 months and one year after implementation. The goal is to reduce the rate from 20% to 5%.*

*To assess ease of use and satisfaction with the new system from staff.*

**Quality Improvement Model:** Identify the QI model to be used in your study

***Example:***

*We will follow the PDSA model (Plan, Do, Study, Act) for this study. As the implementation has already been planned and executed (Plan and Do phases), we plan to focus on the Study and Act phases of the model. We will determine the effect of our intervention on our key metrics. Based upon the results, we will determine if further modifications in our medication ordering protocol are necessary.*

**Description of Initiative:** Describe the quality initiative to be assessed.

***Example:***

*Setting for the study: General Hospital*

Study Timeline

*Staff education/training on the system (11/1/12 – 12/31/12): this will involve a series of computer training sessions on the new system for all staff.*

*System Live: 1/1/2013*

*Error rate/staff feedback assessment: 3 months, 6 months, one year post implementation*

*Initiative follow-up procedures: The medication error rates at the various time points will be compared to the previous year’s rates. A random sample of 5% of all medications prescribed during each time period will be obtained. Using this list, the QI team will determine whether the medication in question was appropriately prescribed to the patient. For quality control purposes, all medication errors will be reviewed by at least two of the team members. In addition, 10% of the medications assessed to be dispensed correctly will be reviewed by one of the other team members to confirm this finding. Staff surveys will be collected from 1/1/14 through 1/30/14 using the SurveyMonkey Platform. Data collected from the surveys will be anonymous.*

***Key metrics:***Describe any outcome variables for the study that will be responsive to the initiative.

***Example:*** *rate of medication errors at 3 months, 6 months and one year, staff feedback*

***Data review/Analysis:*** Describe how you will analyze your data

***Example:*** *Descriptive data will be summarized for the study. Comparisons between the medication error rates will be performed. Staff survey data will be compiled and reviewed for suggestions/satisfaction rates.*

***Next Steps:*** Based upon your findings, describe how you will proceed.

***Example:*** *If we are able to demonstrate a reduction in the medical error rate to less than 5%, the intervention will have been considered to be a success and no further action will be taken. If the rate has been decreased, but is greater than 6%, we will set up a multidisciplinary focus group to determine what other changes can be implemented to help us to further decrease the medical error rate.*

***References (if applicable):*** Use this section to provide all of the references used throughout your study. Pick a format and use it consistently.

***Example:***

1. *Peat B, Albery E, Jones K, Pigott R: Tailoring Velpharyngeal Surgery: The Influence of Etiology and Type of Operation. Plast Reconstr Surg 1994:93:948-953.*

2. *Orticochea M: A Review of 236 Cleft Palate Patients Treated with Dynamic Muscle Sphincter. Plast Reconstr Surg 1983:71:180-188.*

*3. Ren Y, Wang G: A Modified Palatopharyngeous Flap Operation and its Application in the Correction of Velopharyngeal Incompetence. Plast Reconstr Surg 1993:91:612-617.*