Touro University California

School of Nursing

MSN Culminating Quality Improvement Project Handbook

August 2017

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Introduction

This handbook has been developed to serve as a roadmap to the processes, procedures and requirements of the MSN Culminating Quality Improvement (QI) Project. The MSN culminating QI project is developed, implemented, and disseminated over two-three semesters and is supported by content delivered throughout the MSN program.

Overview of Culminating Quality Improvement Project

The MSN program culminates in the successful completion of the quality improvement (QI) project that is completed over two to three semesters. The QI project integrates principles of graduate education, CNL role development, and direct care experiences to design, implement, evaluate, and disseminate an outcome-based model of health care improvement; reflective of the CNL role in complex health care systems. Each student collaborates with an agency to address a real-world problem in the clinical setting within a specific microsystem. The final product of the project is a professional poster and scholarly paper.

Development and Progression of the Culminating QI Project

	Spring Semester Session 2	Summer Semester Session III	Fall Semester Session IV	Fall Semester Session V
Identify broad area of interest	X			
Identify 3 key articles of interest	X			
Agency placement	X			
QI Project PICOT Question	X			
QI Project Proposal approval		X		
QI Project Implementation		X	X	
Outcome Analysis			X	X
Report development			X	X
Poster Development				X
Poster Presentation				X

MSN Project Advisor

The faculty advisor will serve as the QI Project advisor and provides academic guidance and mentoring to the MSN student in concert with the preceptor. The student should meet regularly with the advisor for assistance with project development, implementation, analysis and dissemination of results. The faculty advisor does not need to be an expert in the student's area of interest.

QI Project Proposal

The QI proposal should be developed with the guidance of the faculty advisor and is a minimum two-step process.

1. The student submits the proposal worksheet to the faculty advisor for approval.

2. Once approved by the faculty advisor, the proposal is transcribed to the SON IRB form for Sub-Committee final approval.
3. Upon approval by the SON IRB sub-committee the student may need to submit their proposal to the agency for further approval.

This is typically an iterative process and requires the document to be resubmitted until all the approval standards are met. Once approved, the QI project may be subject to approval by the agency where the project is conducted. Implementation is dependent on all appropriate approvals. At no time prior to approval from the SON IRB sub-committee or agency approval is the student to start any aspect of the project.

QI Project Timeline and Instructions for Writing the Final Paper

INSTRUCTIONS

- ❖ This instructional guide is to be used to complete the QI Project and Final Paper for NRSC 616.
- ❖ Customization of the Final QI Paper template is NOT permitted. A copy of this document will be provided to your clinical preceptor.
- ❖ Adherence to the deliverable timeline is REQUIRED.
- ❖ Final QI Paper MUST BE submitted using NRSC 616 template.

REFERENCES

Roush, K. (2015). *A Nurse's Step-By-Step Guide to Writing Your Dissertation or Capstone*. Indianapolis: Dustin Sullivan. ISBN: 978 1940446080

Timeline	Graded Assignment	Deliverables	Page Limit
	N/A	**Project Proposal Submission - SON**	**N/A**
	N/A	**Organizational IRB Submission** (only if required by the clinical agency)	**N/A**
	N/A	**Title Page**	**N/A**
	#7	**Abstract (Written after all chapters completed)** ● Single spaced, 120-250 words maximum ● Reflecting: ○ QI question ○ Participants ○ Methodology ○ General results ○ Implications of the project	**1**

	#1	**Introduction (Roush 2015)** - Background o Microsystem assessment ▪ Prevalence of the problem ▪ Stakeholders ▪ Root Cause Analysis/Ishikawa Diagram o Impact of problem to nursing ▪ Patient care/outcomes ▪ Policy ▪ Finance o Definitions o PICO Question/Problem Statement o Specific Aims	**1.5**

	#2	**Literature Review - pg 19** (Roush, 2015) - Synthesis of Selected Articles from EBP table (min. 5 articles) - Summarize the relevant finding of current literature	**2**
	#3	**Methodology – pg 37** (Roush, 2015) - Design of Study o Quantitative vs Qualitative o Setting o Sample (size, who, recruitment) o Tools used o Consent (copy of consent in appendix) o Data collection o Data analysis	**1.5**
	N/A	**Implement practice change and Data Collection**	**N/A**
	#4	**Results – pg 69** (Roush, 2015) - Preliminary analysis of data - Response rates - Sample size/demographics - Findings (descriptive analysis/statistical) - Project evaluation and outcomes	**1**
	#5	**Discussion – pg 87** (Roush, 2015) - Review of the problem - Discussing the sample - What do your results mean? - Discuss bias, generalization, reliability, validity - Impact of results to nursing o Patient care/outcomes o Policy o Finance	**2**
	#6	**Conclusion - pg 101**(Roush, 2015)	**1**
	N/A	**Appendices** (tables, charts, graphs, etc.)	**N/A**
	N/A	**References** (5 articles minimum)	**N/A**

	#8	**Final QI Paper (Assignments 1-7)** - The paper should be free of spelling, grammar, and punctuation errors and must be formatted in APA with a cover sheet, running head, and appropriate margins, font, citations and reference list.	**10**
		Poster Presentation Farragut Inn	

Instructions on Creating Culminating Quality Improvement Project Posters

Preparation

- Draw a mock-up of sections you need and possible layouts
- Leave enough time to prepare and check turnaround time for printing
- Check to see if printing service will give you a "proof"—sometimes things don't translate well from one system/printer to another and some details you can't see easily in PowerPoint
- Check requirements for printing services (e.g. resolution for images, max printing size, whether fonts need to be embedded in PowerPoint presentation)

Content

- Keep purpose in mind (your purpose and conference purpose)
- Consider audience (technical background, etc.)
- Think "press conference"—max 2 minutes/2 pages of info
- Some content can be omitted from poster and included in handouts and/or published papers (e.g. extensive lit reviews or bibliography, complex tables)

Size

- 36" x 48"

Design

- Sell your content
- Keep material simple
- Be selective in what you present
- You want passers-by (who are also eating breakfast, drinking coffee, and talking) to get something from your poster in 30 seconds
- Use logical order (people are used to reading in columns (top to bottom) from left to right, or in rows (left to right) from top to bottom
- Label sections to help guide—e.g. use research journal manuscript sections or some derivation thereof as appropriate to your content
    - In addition to title, authors, affiliation, and usually acknowledgements, you should include "what, why, how, results, so what?"
      For example, use one or more relevant heading from each category:
      What: objectives, purpose, hypotheses
      Why: background, theory, context

How: methods, design, sample, data, measures, analyses
Results
So what?: summary, conclusions, implications, limitations, further study

- Posters are not manuscripts, so don't try to include the same detail as in a paper
- Several examples are available to use as formats (see NRSC 616 Blackboard site)

Color

- High contrast (e.g. dark text and light background)
- Beware of large blocks of bright colors
- Beware of dark or patterned backgrounds
- Gradient backgrounds sometimes don't print well
- Use color to emphasize/differentiate/add interest (not just because they're there)

Font

- Large enough to see from at least 5-8 feet, e.g. 14 (if printed at 200%) for text, larger for section headings and even larger for title (to be seen from 15-20 feet)
- Simple font (e.g. Arial)
- Italic and bold work better for emphasis than underlining
- Keep to one (or very few) font types
- Minimize use of all caps

Graphs/pictures

- Should be understandable, readable, relevant
- Follow basic guidelines for statistical graphics
- Beware of clipart (use only when it clarifies, illustrates, etc.—not just because it's cute)
- Use appropriate resolution for images/photos
- Minimize use of multitudes of numbers—use graphs whenever possible
- jpg files usually more efficient than other types for images

Check/check/check

- Spelling
- That elements line up
- Consistency of style, fonts, etc.

A few notes on PowerPoint

- Set slide size at ½ the poster finished width and length you want (then you'll specify to print at 200%)
- Use the SON poster template.
- Guide lines are very useful for lining up text boxes
- Check that font, color, margin, indent markers, and line spacing are consistent in every text box
- Images and objects should be inserted, not copy/paste

Guidelines for acknowledgement

Authors should publicly thank those people and organizations that supported the work submitted for public presentation.

- Prior to acknowledging an organization or person, confer in advance with the person or organization whose name you intend to publicly recognize.
- Some organizations that provide grant funding will require acknowledgement and may have a preferred statement about how they wish to be acknowledged.

Appendix A: Determining the Level of Risk for the Culminating QI Project

Before starting any Quality Improvement Project students must secure approval from their faculty advisor and complete the *Request for Review by SON Project Review Committee.* Review the following information regarding to help in determining the level of risk for human subjects involved in the project

Level of Risk
The following definitions are utilized when reviewing protocols to determine their level of risk to participants:

1. **Exempt**: Some categories of research are considered "exempt" under federal regulations. Examples include research in established courses on the effectiveness of instructional techniques, observational research on adults (but not children or minors) when the observations are recorded in a way that does not allow individual participants to be identified, reviews of pre-existing records or surveys that are completely anonymous, and studies which evaluate public service or benefit programs. For more specific information, see Federal Policy §46.101(b).
2. **No Risk**: Research is approved as "no risk" when no harm or discomfort is anticipated for participants.
3. **Minimal Risk**: Research is approved at "minimal risk" when the probability and magnitude of harm or discomfort anticipated for participants are no greater than what might be encountered in daily life or during the performance of routine physical or psychological examinations or tests [Federal Policy §46.102(i)]. (Note that only "minimal risk" is defined in the federal regulations.)
4. **At Risk**: Research is approved as "at risk" when the probability and/or the magnitude of possible harm (physical, psychological, social, or economic) from participation in a research study are more than minimal.

The following descriptions provide additional information about some possible kinds of risks that may occur in research studies:

1. **Physical Harm**: An example of minor physical harm would be the pain associated with taking a blood sample from a vein. Note, however, that taking a blood sample could be a significant risk to a hemophiliac; participants should be screened for this condition if the research is to be considered minimal risk. Similarly, outdoor exercises that might be considered relatively safe for healthy adults could be dangerous for persons with asthma.

2. **Psychological Harm**: An example of psychological harm would be stress or feelings of guilt or embarrassment from thinking or talking about one's own behavior or attitudes on sensitive topics such as drug use, sexual orientation, selfishness, or violence. These feelings may be aroused from being interviewed or from filling out a questionnaire. Another kind of risk would be invasion of privacy, for example, from covert observation (even in a public place) of behavior that participants would likely consider private. Still another risk of psychological harm occurs when there is inadequate protection for the confidentiality of data that has been given voluntarily (e.g., by retaining audiotapes or videotapes longer than is necessary to analyze the relevant information).

3. **Social and Economic Harm**: Some invasions of privacy or breaches of confidentiality could result in embarrassment or harm to a participant's reputation within his or her business or social group, a loss of employment, or criminal prosecution. Areas of

particular sensitivity include such topics as alcohol or drug abuse, child or partner abuse, and sexual behavior.

4. **Inadequate Protection for the Confidentiality of Research Data**: Where identifiers of individual participants are not required by the design of the research study, none should be recorded. If identifiers are recorded, they should be separated, if possible, from the data; stored securely, with linkage restored only when necessary to conduct the research; and destroyed when they are no longer needed. More elaborate procedures may be needed in some studies, either to give participants the confidence they need to answer questions truthfully (e.g., promising to submit course grades before analyzing data from one's own students) or to enable the researcher to offer honest assurances of confidentiality. Even when participants are otherwise anonymous, there may be a danger of deducing the identity of individual participants by combining specific pieces of information collected during the research about the participants. Additional precautions may be needed to deal with these circumstances.

In some projects, keeping the identity of participants confidential may be as important as or more important than keeping the research data confidential. In those instances, any written record linking participants to the study may be a threat to confidentiality. Even in projects where this is not a concern, no lists should be retained identifying those who elected not to participate.

Where data are being collected about sensitive issues (such as illegal behavior, alcohol or drug use, or sexual practices or orientation), protection of confidentiality consists of more than just preventing accidental disclosure of the data. There have been instances where the identities of participants, or research data about particular participants, have been sought by law enforcement agencies, sometimes by subpoena and with the threat of incarcerating an uncooperative researcher. Some investigators may need to obtain a federal certificate of confidentiality [Public Health Service Act §301(d)] to protect the privacy of their participants. The certificate protects the researcher from being compelled to provide the names or other identifying characteristics of research participants in any federal, state, or local civil, criminal, administrative, legislative, or other proceeding. (Its precedence over state law has been upheld in the New York Court of Appeals.) The certificate does not protect identifiable data that the participant may disclose about other people.

5. **Informed Consent**

   Informed consent assures that prospective participants understand the nature of the project and can knowledgeably and voluntarily decide whether or not to participate. It is a continuing process, not just a piece of paper; especially in a lengthy study, it may be necessary to obtain consent on more than one occasion. It protects both the participant and the investigator, who otherwise faces legal hazards. Investigators may seek consent only under circumstances that provide prospective participants or their representatives sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. Furthermore, the information must be written in language that is understandable to the participants. If the prospective participants include persons who are unlikely to be familiar with specific technical terms, persons with limited verbal or cognitive skills, or persons whose primary language is not English, special care must be taken to ensure that both oral presentations and written consent forms are comprehensible to all participants. When participants may include members of a vulnerable population (such as children, elderly persons, prisoners, or economically or educationally disadvantaged persons), additional safeguards are needed to protect the

rights and welfare of those subjects.

6. **Children/Adolescents**
   When children and/or adolescents are participants in a research study, the investigator must solicit both the assent of the children and the permission of their parents or guardians. In most cases, research involving children and/or adolescents will require additional review at the University level.

7. **Coercion**
   To minimize the possibility of coercion or undue influence, it is generally preferred that participants be recruited by open, written invitation rather than by personal solicitation. For similar reasons, it is also preferred that supervisors not include their own employees in research. If advertising will be used to recruit participants, this information and the associated materials must be included with the protocol submission. This is done to assure that the information will not be misleading to potential participants. Similarly, if participants are to be paid for their time, the protocol must include the amount of the payment and provisions for full, partial, or no payment (for example, if a participant withdraws part way through the research) to assure that participants will not be unduly influenced by the payment.

8. **Exception to Consent Form**
   In most cases, federal regulations require that participants sign a written consent form [Federal Policy §46.117], although the consent document is not a substitute for discussion of the relevant information with prospective participants. Participants must be given a clear and fair explanation of the research procedures, their risks and benefits, and provisions for confidentiality in the research. (See Appendix B, C, & D for examples of consent forms and guidelines for constructing a consent form.) Each participant must provide informed consent prior to participation. The person who signed the consent form must be given a copy as a reference and reminder of the information conveyed. A "short form" may sometimes be approved for the consent [Federal Policy §46.117(b)(2)]. This means that the information is presented orally to prospective participants without a written version of it in the consent document. The protocol submission must include the written summary of what will be presented orally.

Appendix B: Constructing a Consent Form

Federal regulations require that the following information be provided to prospective participants when obtaining consent [Federal Policy §46.116(a)]:

1. An explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
2. A description of any reasonably foreseeable risks or discomforts to the subject;
3. A description of any benefits to the subject or to others which may reasonably be expected from the research;
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
5. A statement describing the extent to which confidentiality of records identifying the subject will be maintained;
6. For projects involving more than minimal risk, an explanation as to whether any compensation and whether any medical treatments are available if injury occurs, and if so, what they consist of, or where further information may be obtained;
7. An explanation of whom to contact for answers to pertinent questions about the research and about the rights of research subjects, and whom to contact in the event of a research-related injury to the subject; and
8. A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

When appropriate, the following additional information must also be provided to subjects [Federal Policy §46.116(b)]:

1. A statement that the particular treatment or procedure may involve risks to the subject which are currently unforeseeable;
2. Anticipated circumstances under which the subject's participation may be discontinued by the investigator without the subject's consent;
3. Any additional costs to the subject that may result from participation in the research;
4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
5. A statement that significant new findings developed during the course of the research which might affect the subject's willingness to continue participation will be provided to the subject; and
6. The approximate number of subjects involved in the study.

Appendix C: Example of a "No Risk" Consent Form

Consent to Participate in QI Project

Purpose of Research

You are being asked to participate in a project which will be conducted by *insert name* in the School of Nursing at Touro University California. The purpose of the study is to investigate *insert purpose*. This information is important because *insert why*.

Research Procedures

You will be asked to complete a survey….

Risks

It is not anticipated that there will be any health risks to completing this survey.

Benefits

You may not personally benefit from participating in this research. However, *insert benefit to the profession of nursing.*

Confidentiality

There are no identifying marks on the survey and your participation in this study will also be kept confidential. However, the results of the study as a whole may be shared with the agency and the nursing community.

Compensation (optional)

You will receive *insert enticement.*

Contact Information

If you have any questions about this research, you may contact *name* at *phone number or e-mail.*

You may decline to be a participant in this study without any consequences. Your signature below indicates that you have read this page and agree to participate in the research.

_____ _____

Signature of Participant Date

Appendix D: Example of a "Minimal Risk" Consent Form

Purpose of Research

You are being asked to participate in a project which will be conducted by *insert name* in the School of Nursing at Touro University California. The purpose of the project is to *insert purpose*. This information is important because *insert why*.

Research Procedures

You will be asked to complete several questionnaires about *your academic abilities, your personal traits and values, and your relationships with other students, family, and friends*. The questionnaires may require *up to an hour* of your time. *If you agree, you may also be asked later to participate in a focus group discussion with about five other students on these topics. The focus group discussion could also last up to one hour.*

Risks

Some of the items in the questionnaires may seem *personal*, but you don't have to answer any question if you don't want to. Some of the topics in the focus group discussion may also seem personal, but you may participate as much or as little in the discussion as you wish.

Benefits

You may gain additional insight into *factors that affect success in college*, or you may not personally benefit from participating in this research. It is hoped that the results of the study will be beneficial *for programs designed to encourage students to remain in college*.

Confidentiality

Your responses on the questionnaires will be anonymous. Only first names will be used in the focus groups, and you may use something other than your real name if you wish. With the permission of everyone in the group, the focus group discussion will be audio taped. Those tapes will be destroyed as soon as the discussions have been transcribed, and in any event no later than one year after they were made. Until that time, they will be stored in a secure location. Only group results for the project will be reported.

Compensation

You will not receive any compensation for participating in this study.

Contact Information

If you have any questions about this research, you may contact *name* at *phone number or e-mail.*

Your participation is voluntary and you may decline to be a participant in this study without any consequences. Your signature below indicates that you have read this page and agree to participate in the research.

_____ _____

Signature of Participant Date

Appendix E: Quality Improvement Project Instructions

Touro University California School of Nursing IRB

(Do not submit these instruction sheets)

Projects that are thought to be quality improvement (QI) projects may be submitted to the TUC SON IRB for an authoritative determination of their status by using the "Request for Determination that Project is QI Form". As a result of this IRB review, the submission will be declared to be exempt from further IRB review, or determined to be a research study involving humans that is subject to further IRB review.

The template presented below is designed for projects involving the translation of existing knowledge into clinical practice. Evaluating the effectiveness of knowledge implementation in creating clinical practice change is measured by the QI project outcomes. Since the focus of these projects does not fit the definition of research under 45 CFR 46.102(d), they will be evaluated as not involving research with humans. For such projects, privacy and confidentiality regulations (HIPAA) must still be followed. The TUC SON IRB will review and provide consultative assistance, but is not responsible for approving how privacy, data storage and confidentiality measures are implemented in the quality improvement project. A clinical site letter is requested to document support and agreement with this practice change by individuals engaged in direct clinical care at the site where the practice change is to occur.

The project summary for the IRB should be no more than 5 pages. Please use the template in Appendix F to complete the proposal. A letter of support from the clinical site where the project is to be implemented should be included as well.

Project Title

Statement of the Problem/PICO(T)

I. Introduction

Purpose

Concisely describe the issue addressed by this quality improvement project. Provide support that the focus of this project is to implement existing knowledge in clinical practice and not to generate new knowledge. Identify the purpose of this project and list specific aims or goals to be accomplished.

Quality/Safety process or patient experience to be addressed

II. Background and Significance

Why is this issue a problem?
How do you know it is a problem?
Why should we care?
What are the outcomes now? What is the anticipated outcome?

III. Literature Review and Synthesis

Include search strategies and critically summarize the evidence that supports the quality improvement project. The evidence should be convincing to clearly support practice change. Demonstrate how the translation of evidence will be implemented in clinical practice. Emphasize that this project will not produce new knowledge (research) but is to implement evidence into clinical practice (quality improvement).

IV. Project Details

Include the following information in this section:

- Describe the setting for the QI project (unit, number of patients/nurses)
- Describe the sample (who will be involved, how many, inclusion criteria)
- Quality improvement that will change practice
- Who are the stakeholders; who needs to be involved in the planning, intervention, and evaluation processes?
- Identify the quality improvement strategy (provide details of how the evidence will influence practice change and the specific strategies or steps for implementation; include discussion of key clinical staff engaged in the project; describe the evidence implementation's potential for sustainability
- Describe the timeline for completion of the project. Include when data collection is to be initiated, when the project implementation phase occurs, and when post implementation data will be collected.
- Identify the level of risk to the sample population and how the risk (if any) will be mitigated

V. Data Collection and Evaluation

Tools: Provide a concise description of how data will be collected (include copies of surveys, questionnaires, focus group questions etc.)
Data Collection Instructions: Include how patient data will be identified, who is involved with data collection, and what data will be obtained. Describe where this information is found and how it will be extracted. Is consent needed (include form with this packet)?
Data Security:

- Discuss how the patient's and/or nurse's privacy will be protected.
- Describe what media type will be used to store the data (paper or electronic file or both).

- Describe what Protected Health Information (PHI), if any, will be stored.
- Specify whether PHI will be destroyed once all data collection is completed.
- Specify how data will be de-identified.
- Specify the location where the paper or electronic file will be stored.
- Specify the location where the data will be secured, who will have access to this information and measures to assure confidentiality is maintained.
- Indicate how you intend to use Protected Health Information of patients whose information is used to measure the change in practice as a result of the evidence-based implementation project.

Outcome Indicators: Describe how the quality improvement project will be evaluated and what statistical measures will be used**.**

Descriptive Statistics: What information will be identified to describe the population/sample for the QI project?

VI. Conclusion

Compose a summary of the project to include a statement of the purpose, the intervention, and the evaluation processes.

VI. References

Include all references in APA format.

Letter of support from the clinical setting

A clinical site letter from a manager or director of the department where the project is being conducted should be included to document support and agreement with this practice change by individuals engaged in clinical care. The support letter should include the signature of the clinical administrator or clinical leader who has the authority to approve the implementation of practice change (**should not be the preceptor; unless the preceptor is the department manager/director who has authority over that clinical area**).

Appendix F: Quality Improvement Summary Template

Student Name:
The Project is an MSN _____or DNP _____ final project.

- The Faculty Advisor for this project is: _____
- The Student Preceptor for this project is: _____
- The Institution where the project will be conducted: _____

Letter of administrative approval from the Clinical Site/Setting is included: Yes ___ No ___

Project Title:

Statement of the Problem/PICO(T):

I. INTRODUCTION
   a. Purpose
   b. Quality/Safety processes or patient experience to be address

II. BACKGROUND AND SIGNIFICANCE

III. LITERATURE REVIEW
   a. Search strategies
   b. Summary and critical appraisal of the evidence

IV. PROJECT DETAILS
   a. Setting
   b. Change in process
   c. Key stakeholders
   d. Quality improvement strategy
   e. Timeline
   f. Level of risk

V. DATA COLLECTION AND EVALUATION
   a. Data collection tools
   b. Data collection instructions
   c. Data security
   d. Outcome indicators
   e. Descriptive statistics

VI. CONCLUSION
VII. REFERENCES
VIII. ATTACHMENTS

Appendix G: Determination that Project is Quality Improvement

3. Will this project be supported by an external entity that is NOT a research grant?

☐ **No** ☐ **Yes**

4. Name of funding agency or source:

5. Title of Grant:

6. Does the funding agency require an IRB review?

☐ **No** ☐ **Yes.** *[Please submit this project for IRB review using the appropriate New Project Application]*

Part C – Project Information

1. Please provide a synopsis of the proposed project *(or attach proposal and supporting documents)***.**

2. Please identify the intent/objectives of the proposed project.

Part D – Regulatory Criteria for Clinical Quality Improvement/Measurement

Instructions: Answer **YES** or **NO** to each of the following statements about QI projects.

1. The aim(s) of the project is to improve the process or delivery of care with established /accepted quality standards, or to implement change according to mandates of the organization's Clinical QI programs and or organizational leadership. There is no intention of using the data for research purposes.

☐ **No** ☐ **Yes**

2. The specific aim is to improve performance on a specific service or program in the hospital and is part of usual care. <u>All participants will receive standard of care</u>.

☐ **No** ☐ **Yes**

3. The project is <u>not</u> designed to answer a research question or test a hypothesis and is <u>not</u> intended to develop or contribute to generalizable knowledge.

☐ **No** ☐ **Yes**

4. The project does <u>not</u> follow a research design (e.g., hypothesis testing or group comparison (randomization, control groups, prospective comparison groups, cross-sectional, case-control)). The project does <u>not</u> follow a protocol that over-rides clinical decision-making.

☐ **No** ☐ **Yes**

5. The project involves implementation of established and tested quality standards and/or systematic monitoring, assessment or evaluation of the organization to ensure that existing quality standards are being met. The project does <u>not</u> develop paradigms or untested methods or new untested standards.

☐ **No** ☐ **Yes**

6. The project involves implementation of care practices and interventions that are consensus-based or evidence-based. The project does <u>not</u> seek to test an intervention that is beyond current science and experience.

☐ **No** ☐ **Yes**

7. The project is conducted by staff where the project will take place, and involves staff who are working at, or patients who are seen within the institution.

☐ **No** ☐ **Yes**

8. The project has no funding from federal agencies or research-focused organizations, and is not receiving funding for implementation research.

☐ **No** ☐ **Yes**

9. The clinical practice unit (hospital, clinic, division, or care group) agrees that this is a QI project that will be implemented to improve the process or delivery of care (i.e., not a personal research project that is dependent upon the voluntary participation of your colleagues, students and/or patients).

☐ **No** ☐ **Yes**

10. If there is an intent to, or possibility of publishing your work, you and your Department/QI Oversight group are comfortable with the following statement in your methods section*: "This project was undertaken as a Quality Improvement Initiative at X hospital or clinic, and as such was not formally supervised by the Institutional Review Board per their policies."*

☐ **No** ☐ **Yes**

11. The purpose of this project is maintenance of certification as required by your profession.

☐ **No** ☐ **Yes**

Part E – Signature

As the leader of this project, my signature below provides written assurance that I have reviewed this submission and that all information provided is accurate.

_____ _____ _____

Signature **Date** **Print name**

Appendix H: Pre-Submission Checklist

To assure prompt review of your application, ALL students must complete this checklist:

- ✓ Have you met with your faculty advisor before preparing your proposal? Has your faculty advisor thoroughly reviewed all of your materials before you submitted your proposal?

- ✓ Have you written an appropriate answer for each question on the proposal form? (Please do not attach research proposals, grant applications, etc. as the committee cannot read such documents.

- ✓ Have you answered all of the questions on the application form? (Please enter "N/A" if a particular question does not apply to your project.)

- ✓ Have you provided an e-mail address and a phone number where you can be reached on the application?

- ✓ Have you signed the proposal form?

- ✓ Have you included your consent form with your proposal?

- ✓ Does your consent form clearly describe what participants will be asked to do in your project? Does it clearly describe any direct benefit they will receive as a result of their participation? Does it clearly describe any risks they will be exposed to during their participation, and what you will do to minimize those risks?

- ✓ Have you included with your proposal any screening forms that will be used to determine the eligibility of participants for your research?

- ✓ Have you included with your proposal all tests, questionnaires, surveys, interview questions, focus group questions, flyers, teaching materials etc. that will be used in your project?

- ✓ Have you checked the *grammar and spelling* throughout all of your documents?