School of Nursing and Health Professions IRBPHS Approval of Practicum or Project Activity

All research with human subjects conducted by faculty or students at USF requires prior approval by the University IRBPHS Committee. Refer to USF IRB guidelines (USF Connect) for current procedures regarding application for approval of your research. Any research conducted by students must have faculty support and approval prior to submission of the application to the University IRB Committee. Do <u>not</u> proceed with any type of recruitment, data collection or analysis until you receive written approval from the University IRBPHS Committee.

All student clinical projects must receive approval by the Supervising Faculty (i.e., DNP Committee Chair, CNL Internship Faculty). Department approval is necessary prior to enrollment in Practicum, Internship or Residency courses that require student design and completion of evidence-based change of practice projects. Approval forms (Statement of Determination) can be downloaded from the BSN, MSN or DNP Student Portal.. Normally, DNP, CNL and BSN student projects are evidence-based change of practice projects rather than research projects and do not require IRB submission.

Evidence-based Projects, Research and IRBPHS

An evidence-based change in practice project is based on current evidence in the literature or internal institutional evidence such as epidemiological or financial data, patient satisfaction scores and other outcome data. Standardized methods such as PDSA, LEAN, 5-P and Process Mapping are used to implement changes that will improve the quality of care, systems or processes, or meet regulatory and accreditation requirements. Use of the evidence is not research and should not normally include research protocols.

BSN students will focus on patient/family, care delivery team. CNL students have a focus on microsystem changes, while DNP students will focus on meso and macrosystem projects.

Quality Improvement is defined as "a systematic pattern of actions that is constantly optimizing productivity, communication, and value within an organization in order to achieve the aim of measuring the attributes, properties, and characteristics of a product/service in the context of the expectations and needs of customers and users of that product". [Source: The Institute of Medicine]

• QI projects do not require IRB approval

Research is defined as "a systematic investigation, including research development,

testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities."

http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.102

• All research involving human subjects requires IRB approval.

Student Projects might use mixed methods, whereby research activity is combined with QI/ Process improvement. In these cases federal guidelines state "most quality improvement efforts are not research subject to the HHS protection of human subjects regulations. However, in some cases quality improvement activities are designed to accomplish a research purpose as well as the purpose of improving the quality of care and in these cases, the regulations for the protection of subjects in research (45 CFR part 46) may apply. "

http://answers.hhs.gov/ohrp/categories/1569

• Any student or faculty projects that include research activity or potential research activity must have prior IRB approval.

Definition of Human Subjects

The federal regulation used to define human subjects will be used by SONHP faculty, Committee Chairs and the Departments to determine whether student projects involve research and must have IRB approval.

- <u>DHHS definition</u> a living individual about whom an investigator conducting research obtains (1) data through <u>intervention</u> or <u>interaction</u> with the individual; or (2) identifiable <u>private information</u>.
 - Intervention_includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
 - o Interaction includes communication or interpersonal contact between investigator and subject.
 - O Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

• <u>FDA definition</u>- an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient.

The following examples are NOT human subjects research and therefore do not normally require IRB approval:

- Quality Improvement Projects aimed at improving local systems of care. The intent is to promote <u>"betterment"</u> of a process of care, clinical outcome within the institution.
- Process Improvement- Projects designed to streamline systems of care delivery. Usually designed for cost containment, increased efficiency and effectiveness. May be quality neutral.
- Regulatory or Accreditation Compliance- Projects designed to meet new or revised standards. May include EHR implementation, facilities re-design for seismic or other code updates, and other federal or state mandates.
- Quality Assessment activities that determine whether aspects of practice conform to established standards.
- Quality Assurance Process of reviewing, analyzing or evaluating patient or provider specific data that may indicate (the need for) changes in systems or procedures that improve quality of care. The knowledge generated is typically for local, immediate application within the institution.
- Outcome analysis: Projects in which medical records are reviewed to evaluate the outcome of medical treatment or the course of patients with a specific medical condition. Results are not compared to an established standard.
- o **Resource utilization review**: Medical record review conducted to evaluate the use of resources in a specific health care activity.
- Public health practice: e.g., surveillance (monitoring of diseases) and program evaluation (immunization coverage, or clinical preventive services such as mammography).
- **Education**: transferring information from one group of people to another i.e., teaching somebody something.

 Evidence-based nursing practice change: designed to enhance the well-being of a patient or patient population by using evidence to improve systems, processes or assure regulatory or accreditation compliance.

IRB Approval Necessary to Publish

IRB approval is not necessary to publish or present QI projects and findings as long as the publication or presentation does not refer to the project as research and makes it clear that the publication is the result of a quality / process improvement activity. The following federal guideline makes this clear and can be disseminated to journals that question this determination.

• "the intent to publish is an insufficient criterion for determining whether a quality improvement activity involves research. Planning to publish an account of a quality improvement project does not necessarily mean that the project fits the definition of research; people seek to publish descriptions of non-research activities for a variety of reasons, if they believe others may be interested in learning about those activities. Conversely, a quality improvement project may involve research even if there is no intent to publish the results." http://answers.hhs.gov/ohrp/categories/1569

IRB Exempt Categories of Research:

The following types of research are exempt from IRB approval. 45_CFR_46.101(b)

- 1. Research conducted in established or commonly accepted **educational settings**, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- 2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, **unless**:
 - (i) information obtained is recorded in such a manner that **human subjects can be identified**, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
- 3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public

behavior that is not exempt under paragraph (b)(2) of this section, if:
(i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

- 5. Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:
- (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.
- 6. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

University of San Francisco School of Nursing and Health Professions

Student Project Approval: Statement of Determination

Title of Project:	
Brief Description of Project:	
To qualify as an Evidence-based Change in Practice Project, rather the Project, the criteria outlined in federal guidelines will be used: (http://answers.hhs.gov/ohrp/categories/1569)	an a Research
☐ This project meets the guidelines for an Evidence-based Change is Project as outlined in the Project Checklist (attached). Student may primplementation.	
☐ This project involves research with human subjects and must be su IRB approval before project activity can commence.	ubmitted for
Comments:	
Signature of Supervising Faculty	(date)
Signature of Student	(date)

EVIDENCE-BASED CHANGE OF PRACTICE PROJECT CHECKLIST*

STUDENT NAME: D	_ DATE:		
SUPERVISING FACULTY: .			
Instructions: Answer YES or NO to each of the following statement	ts:		
Project Title:	YES	NO	
The aim of the project is to improve the process or delivery of care with			
established/ accepted standards, or to implement evidence-based change. T	here is		
no intention of using the data for research purposes.			
The specific aim is to improve performance on a specific service or program	m and is		
a part of usual care. ALL participants will receive standard of care.			
The project is NOT designed to follow a research design, e.g., hypothesis t			
or group comparison, randomization, control groups, prospective comparison			
groups, cross-sectional, case control). The project does NOT follow a proto	ocol that		
overrides clinical decision-making.			
The project involves implementation of established and tested quality stand			
and/or systematic monitoring, assessment or evaluation of the organization			
ensure that existing quality standards are being met. The project does NOT			
develop paradigms or untested methods or new untested standards.			
The project involves implementation of care practices and interventions that	at are		
consensus-based or evidence-based. The project does NOT seek to test an			
intervention that is beyond current science and experience.			
The project is conducted by staff where the project will take place and invo			
staff who are working at an agency that has an agreement with USF SONH	iP.		
The project has NO funding from federal agencies or research-focused			
organizations and is not receiving funding for implementation research.			
The agency or clinical practice unit agrees that this is a project that will be			
implemented to improve the process or delivery of care, i.e., not a personal	1		
research project that is dependent upon the voluntary participation of collea	agues,		
students and/ or patients.			
If there is an intent to, or possibility of publishing your work, you and supe	rvising		
faculty and the agency oversight committee are comfortable with the follow	wing		
statement in your methods section: "This project was undertaken as an Ev	ridence-		
based change of practice project at X hospital or agency and as such was r	ıot		
formally supervised by the Institutional Review Board."			

ANSWER KEY: If the answer to **ALL** of these items is yes, the project can be considered an Evidence-based activity that does NOT meet the definition of research. **IRB review is not required. Keep a copy of this checklist in your files.** If the answer to ANY of these questions is **NO**, you must submit for IRB approval.

^{*}Adapted with permission of Elizabeth L. Hohmann, MD, Director and Chair, Partners Human Research Committee, Partners Health System, Boston, MA.

THIS TABLE PROVIDES AN OVERVIEW OF THE DIFFERENCE BETWEEN RESEARCH AND QUALITY OR PROCESS IMPROVEMENT

	RESEARCH	QI/PROCESS IMPROVEMENT
DEFINITION	"A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities, which meet this definition, constitute research for purposes of this policy, whether or not they are conducted or supported under a program, which is considered research for other purposes. For example, some demonstration and service programs may include research activities." http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.102	Assess or improve a process, program or system to improve performance as judged by the evidence, i.e., established/accepted standards
PURPOSE	Answer a question or test a hypothesis	Improve performance/ process or systems
BENEFITS	May or may not benefit current patients, but may benefit future patients	Directly benefits a process, program or system and may or may not directly benefit patients
RISKS	May put subjects at risk	Does not increase risk to patients with exception of possible privacy/ confidentiality concerns
DATA COLLECTION	Systematic data collection	Systematic data collection
DATA ANALYSIS	Statistically prove or disprove hypothesis	Compare a program/ process/ system to an established set of standards